total mass of VOC per volume of coating solids before and after the incinerator, capture efficiency, and the destruction efficiency of the incinerator used to attain compliance with the applicable emission limit specified under § 60.492. The owner or operator shall also include a description of the method used to establish the amount of VOC captured by the capture system and sent to the control device.

(b) Following the initial performance test, each owner or operator shall submit for each semiannual period ending June 30 and December 31 a written report to the Administrator of exceedances of VOC content and incinerator operating temperatures when compliance with § 60.492 is achieved through the use of incineration. All semiannual reports shall be postmarked by the 30th day following the end of each semiannual period. For the purposes of these reports, exceedances are defined as:

(1) Each performance period in which the volume-weighted average of the total mass of VOC per volume of coating solids, after the control device, if capture devices and control systems are used, is greater than the limit specified under § 60.492.

(2) Where compliance with § 60.492 is achieved through the use of thermal incineration, each 3-hour period when cans are processed, during which the average temperature of the device was more than 28° C below the average temperature of the device during the most recent performance test at which destruction efficiency was determined as specified under § 60.493.

(3) Where compliance with § 60.492 is achieved through the use of catalytic incineration, each 3-hour period when cans are being processed, during which the average temperature of the device immediately before the catalyst bed is more than 28° C below the average temperature of the device immediately before the catalyst bed during the most recent performance test at which destruction efficiency was determined as specified under § 60.493 and all 3-hour periods, when cans are being processed during which the average temperature difference across the catalyst bed is less than 80 percent of the average temperature difference across the catalyst bed during the most recent performance test at which destruction efficiency was determined as specified under § 60.493.

(c) Each owner or operator subject to the provisions of this subpart shall maintain at the source, for a period of at least 2 years, records of all data and calculations used to determine VOC emissions from each affected faciity in the initial and monthly performance tests. Where compliance is achieved through the use of thermal incineration, each owner or operator shall maintain, at the source, daily records of the incinerator combustion chamber temperature. If catalytic incineration is used, the owner or operator shall maintain at the source daily records of the gas temperature, both upstream and downstream of the incinerator catalyst bed. Where compliance is achieved through the use of a solvent recovery system, the owner or operator shall maintain at the source daily records of the amount of solvent recovered by the system for each affected facility.

(d) The requirements of this subsection remain in force until and unless EPA, in delegating enforcement authority to a State under Section 111(c) of the Act, approves reporting requirements or an alternative means of compliance surveillance adopted by such State. In that event, affected facilities within the State will be relieved of the obligation to comply with this subsection, provided that they comply with the requirements established by the State.

(Approved by the Office of Management and Budget under control number 2060-0001)

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 1714))

§ 60.496 Test methods and procedures.

(a) The reference methods in Appendix A to this part, except as provided in § 60.8, shall be used to conduct performance tests.

(1) Reference Method 24, an equivalent or alternative method approved by the Administrator, or manufacturers formulation for data from which the VOC content of the coatings used for each affected facility can be calculated. In the event of dispute, Reference Method 24 shall be the referee method. When VOC content of waterborne coatings, determined from data generated by Reference Method 24, is used to determine compliance of affected facilities, the results of the Method 24 analysis shall be adjusted as described in Section 4.4 of Method 24.

(2) Reference Method 25 or an equivalent or alternative method for the determination of the VOC concentration in the effluent gas entering and leaving the control device for each stack equipped with an emission control device. The owner or operator shall notify the Administrator 30 days in advance of any State test using Reference Method 25. The following reference methods are to be used in conjunction with Reference Method 25:

(i) Method 1 for sample and velocity traverses,

(ii) Method 2 for velocity and volumetric flow rate,

(iii) Method 3 for gas analysis, and

(iv) Method 4 for stack gas moisture.

(b) For Reference Method 24, the coating sample must be a 1-litre sample collected in a 1-litre container at a point where the sample will be representative of the coating material.

(c) For Reference Method 25, the sampling time for each of three runs must be at least 1 hour. The minimum sample volume must be 0.003 dscm except that shorter sampling times or smaller volumes, when necessitated by process variables or other factors, may be approved by the Administrator. The Administrator will approve the sampling of representative stacks on a case-by-case basis if the owner or operator can demonstrate to the satisfaction of the Administrator that the testing of representative stacks would yield results comparable to those that would be obtained by testing all stacks.

(Sec. 114 of the Clean Air Act as amended (42 U.S.C. 7414))

[FR Doc. 83-23209 Filed 8-24-83; 8:45 am]

BILLING CODE 6560-50-M

federal register

Thursday
August 25, 1983

Part V

Environmental Protection Agency

Approval and Promulgation of Implementation Plans; Requirements for Preparation, Adoption, and Submittal; Proposed Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 51 and 52

[AH-FRL 2406-5]

Requirements for Preparation, Adoption, and Submittal of Implementation Plans; Approval and Promulgation of Implementation Plans

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposal of amendments to regulations.

SUMMARY: EPA here proposes amendments to its regulations concerning the construction of new stationary sources of air pollution and modifications to existing sources which appear at 40 CFR 51.24, 52.21, Appendix S to Part 51, 51.18(j) and 52.24. The amendments relate to: (1) Fugitive emissions, (2) federal enforceability, (3) the requirements for health and welfare equivalence for netting under the definition of "major modification," (4) the definition of "significant," (5) the innovative control technology waiver in the regulations for prevention of significant deterioration ("PSD"), (6) secondary emissions, (7) the crediting of source shutdowns and curtailments as offsets in nonattainment areas, and (8) banking of offsets under 40 CFR Part 51, Appendix S. In addition, EPA gives guidance on: (1) The obligation of a state to cure a violation of a PSD increment for particulate matter, (2) the issuance of a non-PSD permit to a project that would cause or contribute to a violation of a PSD increment, and (3) technology transfer for determinations of "lowest achievable emission rate" for purposes of nonattainment preconstruction review.

EPA is proposing these amendments and giving this guidance in order to meet the terms of a settlement agreement between EPA and a number of industries and trade associations challenging the relevant EPA regulations. *Chemical Manufacturers Ass'n v. EPA*, D.C. Cir. No. 79-1112 (settlement agreement entered into February 22, 1982).

DATES: The period for initial comment on the proposed amendments closes on October 11, 1983. A public hearing on the proposed amendments will be held on September 29, 1983, at 10 a.m. EPA agreed in the settlement agreement not to extend the period for initial comment beyond 60 days. EPA intends not to do so. EPA, however, will hold the public docket for this rulemaking open for 30 days after the close of the initial comment period for the submission of written rebuttal and supplementary information.

ADDRESSES: *Comments.* Comments should be submitted (in triplicate, if possible) to: Central Docket Section (A-130), Environmental Protection Agency, 401 M Street, SW., Washington, D.C. 20460, Attention: Docket No. A-82-23.

Public hearing. Room 5353, Waterside Mall, 401 M Street, SW., Washington, D.C.

Docket. EPA has established a docket for this rulemaking, Docket No. A-82-23, in accordance with Section 307(d) of the Clean Air Act, 42 U.S.C. 7607(d). The docket is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery I, 401 M Street, SW., Washington, D.C. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Kirt Q. Cox, New Source Review Section, Office of Air Quality Planning and Standards, Research Triangle Park, North Carolina 27711; 919-541-5591; FTS-629-5591.

SUPPLEMENTARY INFORMATION:

I. Introduction

In August 1980, EPA extensively revised its regulations concerning the preconstruction review of new and modified stationary sources under the Clean Air Act in response to *Alabama Power Company v. Costle*, 636 F.2d 323 (D.C. Cir., 1979). See 45 FR 52676. Five sets of regulations resulted from those revisions. One set, 40 CFR 51.24 (the "Part 51 PSD regulations"), specifies the minimum requirements that a PSD permit program must contain in order to warrant approval by EPA as a revision to a state implementation plan ("SIP"). Another set, 40 CFR 52.21 (the "Part 52 PSD regulations"), delineates the federal PSD permit program, which currently applies in most states as part of the SIP. Another set, 40 CFR 51.18(j), specifies the elements of an approvable state permit program for preconstruction review for nonattainment purposes. It elaborates on Section 173 of the Act, 42 U.S.C. 7503. The fourth set, 40 CFR Part 51, Appendix S, embodies the "Emissions Offset Interpretative Ruling," which EPA revised previously in January 1979 (44 FR 3274). The fifth set, 40 CFR 52.24, embodies the construction moratorium for certain nonattainment areas.

In the fall of 1980, numerous organizations petitioned the Court of Appeals for the D.C. Circuit to review various provisions of those PSD and nonattainment regulations. Subsequently, the court consolidated those petitions into *Chemical Manufacturers Association ("CMA") v. EPA* (No. 79-1112), a collection of challenges to the 1979 revisions to the Offset Ruling.[1]

In June 1981, EPA began negotiations with the industry petitioners to settle the *CMA* case. In Feburary 1982, EPA entered into a comprehensive settlement agreement with those petitioners. Subsequently, the court granted a stay of the case pending implementation of the agreement.

In Exhibit A of the agreement, EPA committed to propose certain amendments relating to: (1) Fugitive emissions, (2) federal enforceability, (3) the requirement for health and welfare equivalence for netting under the definition of "major modification," (4) the definition of "significant," (5) the innovative control technology waiver for PSD purposes, (6) secondary emissions, (7) the crediting of source shutdowns and curtailments in nonattainment areas, and (8) banking of offsets under the Offset Ruling.[2] EPA also committed to give certain guidance on the following three topics when it proposed those amendments: (1) The obligation of a state to cure a violation of a PSD increment for particulate matter, (2) the issuance of a non-PSD permit to a project that would cause or contribute to a violation of a PSD increment, and (3) technology transfer for determination of "lowest achievable emission rate" ("LAER") for purposes of nonattainment preconstruction review.

The purpose of this notice is to fulfill the commitment EPA made in the settlement agreement to propose those amendments and give that guidance. Although the current senior management of EPA did not make that commitment, it has concluded that EPA should still honor it. These proposals will give the litigants and others a full opportunity to register their views in a public forum. This process, moreover, will require EPA to state a final position on the issues and explain it. The settlement agreement, however, does not bind EPA to any particular result when it takes final action, although it does bind EPA to take such action. The current senior management of EPA intends therefore, to review the comments carefully with an open mind, to take a new look at the

[1] The court also consolidated into *CMA* various petitions for review of further revisions to the Offset Ruling that EPA promulgated in September 1980 (45 FR 59874).

[2] EPA made commitments to propose other amendments. Notices relating to those amendments will appear in the **Federal Register** in due course.

proposals, and to make an independent judgment on their merits.

The balance of the notice first discusses each of the proposed amendments. It then gives guidance on the three topics listed above. Finally, it focuses on certain miscellaneous matters.

II. Proposed Amendments

A. Fugitive Emissions

1. *Background.* The five sets of PSD and nonattainment regulations aim their substantive requirements primarily at new "major stationary sources" and "major modification." [3] In addition, they define "major" in terms of rates of emissions. [4] The emissions of some new projects are largely "fugitive" in origin, that is, they would not pass, and could not resonably be expected to pass, through a stack or other functionally equivalent opening. Whether the substantive PSD or nonattainment preconstruction review requirements apply to a new project at all can depend, therefore, on whether its fugitive emissions are included in quantifying its emissions rates for the purpose of determining whether the project is "major." This notice refers to any such determination as a threshold applicability determination.

Four of the five sets of regulations [5] aim their substantive requirements at a new "major stationary source" or "major modification" only with respect to certain pollutants that the project would emit in "major" or "significant" amounts, depending on the regulations in question. [6] The regulations define "significant," as well as "major," in terms of rates of emissions. [7] Whether the substantive PSD or the nonattainment preconstruction review requirements apply to a new "major" project with respect to a pollutant it would emit can depend, therefore, on whether fugitive emissions of the pollutant are included in determining whether the project would emit the pollutant in "major" or "significant" amounts. This notice refers to any such determination as a pollutant applicability determination.

2. *Alabama Power.* The forerunner of the current PSD regulations required fugitive emissions to be included in any threshold applicability determination, to the extent that they were reasonably quantifiable. *See, e.g.*, 40 CFR 52.21(b)(1)–(3) (1980) (codifying 43 FR 26380, 26403–04 (June 19, 1978)). In establishing that requirement, EPA had assumed that the definitions of "major emitting facility" and "modification" in Section 169 of the Act, 42 U.S.C. 7479, exclusively govern the content of their counterparts in the PSD regulations. Since Section 169 does not distinguish between fugitive and non-fugitive emissions, EPA concluded that fugitive emissions are as eligible for inclusion in threshold applicability determinations as non-fugitive emissions.

In *Alabama Power*, however, the D.C. Circuit held that Section 302, 42 U.S.C. 7602, also controls the content of those regulatory definitions in one critical respect. Section 302 provides in pertinent part that:

> When used in this Act:
>
> * * * * *
>
> (j) *Except as otherwise expressly provided,* the terms "major stationary source" and "major emitting facility" mean any stationary facility or source of air pollutants which directly emits, or has the potential to emit, one hundred tons per year or more of any air pollutant *(including any major emitting facility or source of fugitive emissions of any such pollutant, as determined by rule by the Administrator).* [Emphasis added.]

According to the court, nothing in Section 169 expressly displaces the rulemaking requirement in the parenthetical of Section 302(j). 636 F.2d at 370. As a result, the court held, EPA may require the inclusion of fugitive emissions in threshold applicability determinations for a particular project only if it has first established through rulemaking that fugitives are to be included for that class of projects. *Id.* at 369.

Unfortunately, the court did not specifically list what factors it thought EPA had to consider in such a rulemaking. It did say, however, that:

> EPA's regulation of fugitive emissions has been of special concern to the mining and forestry industries which contend, without serious opposition, that they are incapable of meeting the strict limitations on the emission of particulate matter set by the PSD provisions. . . .
>
> * * * * *
>
> The legislative history of this rulemaking provision [Section 302(j)] is sparse, but *it may well define a legislative response to the policy considerations presented by the regulation of sources where the predominant emissions are fugitive in origin, particularly fugitive dust.* Whatever the motivation of the "rule" provision of 302(j), its existence is unmistakable. Even if the origin of this provision is fortuitous, the provision may be welcomed as serendipitous, *for it gives EPA flexibility to provide industry-by-industry consideration and appropriate tailoring of coverage.* [*Id.* at 369 (emphasis added).]

The forerunner of the current PSD regulations also required fugitive emissions to be included in any pollutant applicability determination. *See, e.g.*, 40 CFR 52.21(b)(1)–(3), (i)(1) (1980). Although that requirement was not at issue in *Alabama Power*, the D.C. Circuit nevertheless indicated that it would have upheld the requirement. It stated that:

> [t]he terms of section 65, which detail the preconstruction review and permit requirements for each new or modified "major emitting facility" *apply with equal force* to fugitive emissions and emissions from industrial point sources. . . .
>
> *EPA is correct that a major emitting facility is subject to the requirements of section 165 for each pollutant it emits irrespective of the manner in which it is emitted.* However, a source emitting large quantities of fugitive emissions may remain outside the definition of major emitting facility and thus may not be subject to the requirements of section 165. [*Id.* at 369 (emphasis added).]

3. Revisions in Response to Alabama Power. In response to the court's interpretation of Section 302(j), EPA proposed amendments to both the PSD and nonattainment regulations that would have excluded fugitive emissions from threshold applicability determinations except as to 30 listed caegories of sources. *E.g.*, 44 FR 51924, 51948 (September 5, 1979). Twenty-eight of the categories corresponded generally to the categories in Section 169(1); the remaining two categories encompassed any source subject to an emissions standard under Sections 111 or 112 of the Act, 42 U.S.C. 7411 or 7412. Surface coal mines were not among the 30 categories. *Id.* at 51931. EPA explained that it was proposing to require the inclusion of fugitive emissions as to the 30 categories because emissions from sources in those categories deteriorate air quality regardless of how they emanate and because the Agency's experience in quantifying fugitive

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[3] For example, the Part 52 PSD regulations require only new "major stationary sources" and "major modifications" that would be located in "clean air" areas to have a PSD permit before construction begins. 40 CFR 52.21(i)(1982)

[4] For example, the Part 52 PSD regulations define "major stationary source" as any stationary source with the "potential to emit" 100 tons per year or more of any pollutant subject to regulation under the Act or 250 tons per year or more of any such pollutant, depending on the nature of the source in question. 40 CFR 52.21(b)(1)(1982).

[5] The construction moratorium, 40 CFR 52.24, simply restricts the construction of a project: it does not require the application of control technology and assessments of air quality impact for the various emissions from the project.

[6] For example, the Part 52 PSD regulations require an applicant for a PSD permit for a "major stationary source" to show that the source would have "best available control technology"("BACT") for each pollutant regulated under the Act that the source would emit in "significant" amounts. 40 CFR 52.21(j)(1982).

[7] For example, the Part 52 PSD regulations provide that emissions of sulfur dioxide are "significant" if they equal or exceed 40 tons per year. 40 CFR 52.21(b)(23)(i)(1982).

emissions from such sources was in general grater than its experience in quantifying fugitive emissions from other sources. *Id.*

During the comment period, various industry representatives contended that: (1) Section 302(j) obliges EPA to determine that reasonably satisfactory methods for the measurement, modeling and control of fugitive emissions [8] from a particular category of sources exist before EPA requires those emissions to be included in threshold applicability determinations for any source in that category, and (2) EPA had failed to do that. 45 FR 52692 (col. 2). Indeed, some contended that EPA had promulgate such methods in the form of regulations. *Id.* at 52690 (col. 3).

In its response to comments, EPA disagreed with those contentions. It pointed out that, according to the D.C. Circuit, Congress intended the substantive PSD requirements to be applied "with equal force" to the fugitive and non-fugitive emissions of any project that would be "major" by virtue of its non-fugitive emissions, even if EPA has yet to determine that there are reasonably satisfactory measurement, modeling, or control methods for the fugitive emissions. *Id.* at 52691 (*quoting* 636 F.2d at 369). Thus, Congress consigned any problems of measurement, modeling and control in those cases to each individual permit proceeding for resolution by the permitting authority. EPA reasoned that, if Congress intended to do that, then it must have intended to consign such problems to the permitting authority also in the case of projects that would be "major" only if their fugitive emissions were counted. *Id.* at 52691, 52692. Hence, the Agency took the position that Section 302(j) obliges it simply to afford the public with an opportunity to oppose the inclusion of fugitive emissions as to a particular category and did not focus comment on the specific grounds for such opposition. Thus, concerns *other* than the availability or adequacy of methods of measurement, modeling and control could have impacted this rulemaking. *Id.* at 52690 (col. 3), 52692 (col. 2).

EPA did not specify what other grounds might exist. But conceivable candidates are adverse economic or social impacts. Thus, EPA implied that it read Section 302(j) to require it to consider any such impacts, if a commenter raised them, and furthermore to determine that the benefits of inclusion outweighed those adverse impacts.

On the basis of this response to comments, EPA, in August 1980, promulgated the substance of the amendments it had proposed. *E.G.*, 45 FR 52739. It put the changes into a different form, however. The new provisions on their face require fugitive emissions to be included in threshold applicability determinations for *any* project, but then exempt from the relevant PSD or nonattainment requirements any project that (1) would be "major" only if fugitive emissions were included and (2) does *not* belong to one of 30 categories. *E.g.*, 40 CFR 52.21(b)(4), (i)(4) (vii)(1981).

4. *Industry Challenges to the Post-Alabama-Power Revisions.* In December 1980, the American Mining Congress and various individual mining companies (collectively, "AMC") petitioned EPA for reconsideration of the new PSD regulations. In Part 1 of the petition, AMC asked EPA to reconsider the provisions which on their face require the fugitive emissions of a mining operation to be included in threshold applicability determinations. AMC pointed out that, even though the regulations would exempt a mining operation that would be "major" only if fugitive emissions were taken into account from the PSD permit requirements, nevertheless they could affect such an operation adversely in other ways.[9] AMC also observed that the preamble to the regulations strongly indicates that EPA did not intend the regulations to affect such an operation in those ways. *See* Petition for Reconsideration of Regulations Relating to the Prevention of Significant Deterioration of Air Quality, Part 1 (December 1, 1980) (hereinafter, "AMC Petition for Reconsideration").

In a letter dated January 19, 1981, EPA granted Part 1 of the AMC petition. The Agency confirmed that it intended to establish that any project which would be "major" only if fugitive emissions were taken into account is not to be considered "major" for *any* PSD purpose, unless the project belongs to one of the 30 listed categories. EPA agreed to amend the regulations to conform them to that intention.

Subsequently, in a brief filed in the *CMA* case, AMC and other industry organizations (collectively, the "industry petitioners") challenged the provisions which require a project that would be "major" only if its fugitive emissions were taken into account to be considered "major" if it belongs to one of the 30 categories. They contended, primarily on the basis of the *Alabama Power* opinion, that the Act required EPA, before it established those provisions, to consider the problems of measuring, modeling and controlling fugitive emissions that are peculiar to each category and then to provide—in the words of that opinion—"appropriate tailoring of coverage." They also contended that the Act required the Agency to consider, on an industry-by-industry basis, the social, economic, health and welfare impacts of including fugitive emissions for applicability purposes. Indeed, they suggested that EPA could decline to require the inclusion of fugitive emissions as to a particular category on the grounds that growth in that industry was important to the economy and that the emissions posed low risks to human health and welfare. Finally, the industry petitioners asserted that EPA entirely failed to meet those requirements of the Act. See Petitioners Brief on Fugitive Emissions and Certain Other Issues, at 12–19 (February 11, 1981) (hereinafter, "Fugitive Emissions Brief").[10]

5. New EPA Interpretations of Section 302(j). After reexamining the parenthetical in Section 302(j) in response to the industry challenges, EPA now sees two closely related interpretations of that provision that appear defensible and worth regulatory consideration, in addition to the interpretation on which the existing rules are based. One is that the parenthetical obliges EPA, before it may require the inclusion of fugitive emissions in threshold applicability determinations for a particular Clean Air Act program and a particular category of sources, only to: (1) Identify those problems the sources would ensounter in that program that are specifically due to the fugitive nature of their emissions and (2) determine that reasonable solutions to those problems exist. For the PSD and nonattainment new source review programs and some source categories, those problems may

[8] The phrase "measurement of fugitive emissions" refers in this notice to the quantification of the rate at which pollutants emanate "fugitively" from a particular activity at a source, for instance, the rate at which particulate matter emanates from an unpaved road at a surface mine due to truck traffic. The pharase "modeling of fugitive emissions" refers to the prediction through mathematical models of the concentrations of a pollutant in the ambient air that would result from fugitive emissions of the pollutant.

[9] For example, such an operation would consume increment even before the baseline date, if construction on it commenced after January 6, 1975. *See* 40 CFR 52.21(b)(13)(ii)(*a*) (1981).

[10] More recently, the American Mining Congress and others stated largely these positions, although in different terms and emphasis, in a letter dated August 5, 1982, in which they commented on an earlier draft of this Federal Register notice. A copy of that letter appears in the docket for this rulemaking.

include problems of measurement, modeling, and control.

The argument for this interpretation runs as follows: The parenthetical plainly requires EPA to make a determination of some sort before it may require the inclusion of fugitive emissions in any threshold applicability determination, whether for the purposes of PSD or nonattainment new source review or some other Clean Air Act program that applies only to "major" projects. While Congress failed in the Act and the legislative history to state explicitly what determination it intended EPA to make, one can nevertheless discern from the focus and effect of the parenthetical what Congress must have intended. The parenthetical distinguishes between sources solely on the basis of how their emissions emanate, that is, whether they are fugitive or not; it ignores both the nature of the sources and of the pollutants they emit. In addition, the parenthetical has the effect of exempting sources whose emissions for all regulated pollutants are predominantly fugitive from preconstruction review and other Clean Air Act programs until EPA lifts the exemption through rulemaking. One might argue this shows that Congress thought that companies with sources of predominantly fugitive emissions could face problems in connection with those programs that stemmed entirely from the fugitive nature of the emissions and, moreover, that those problems were serious enough to warrant protection against them for as long as they might persist. Thus, on this basis, the determination that Congress must have intended EPA to make, with respect to a particular category of sources and a particular program, is that reasonable solutions exist for the problems the sources would encounter in the program that are endemic to the fugitive nature of their emissions.

The second interpretation is that EPA, before it may require the inclusion of fugitive emissions in threshold applicability determinations, need determine only that reasonable solutions exist for the problems of *measurement* that are endemic to the fugitive emissions from those sources. That is, techniques must exist for determining whether the source's fugitive emissions, when added to its stack emissions, would equal or exceed the applicable threshold for classification as a major stationary source or major modification. The definitional sections in which the parenthetical operates—Sections 302(j), 169(1) and 169A(g) (7)—all designate benchmarks for deciding whether a source is "major" for the purposes of various Clean Air Act programs. This strongly suggests that Congress was concerned only with the problems stemming from the fugitive nature of emissions that companies would face in threshold applicability determinations—namely, measurement problems—and not also with whatever modeling and control problems the source might encounter in the various Clean Air Act programs, such as PSD or nonattainment new source review.[11]

6. *Choice of Interpretations.* EPA has concluded preliminarily—subject to comment and further deliberation—that these two new interpretations are stronger than either the one EPA espoused in the preamble to the August 1980 amendments or the one industry petitioners advocate in their brief. EPA, in not previously emphasizing consideration of the availability of reasonable methods of measurement, modeling and control, relied on the assumption that Congress would have treated all sources of fugitive emissions identically, whether or not they were already subject to review on account of their non-fugitive emissions. That assumption, however, is not necessarily true. For instance, a major hurdle that a company would face in attempting to obtain a permit for a source of fugitive emissions is having to show that the source would not cause or contribute to concentrations in excess of the applicable NAAQS or PSD increments. If no reasonably accurate methods of measurement and modeling for the fugitive emissions were in existence, then the company would have the burden, at least initially, of developing such methods itself or showing that their development would be impossible or too costly. Contrary to the premise of EPA's earlier argument, Congress may well have been willing to let a company bear this burden if its source would be subject to review anyway because of non-fugitive emissions, but not if the source would not be subject to review if fugitive emissions were ignored. While this is a difference of degree only, it is nevertheless arguably large enough to be a reasonable basis for a difference in treatment.

Industry, in asserting that EPA must determine that the benefits of preconstruction review for a particular category outweigh the costs, impliedly claimed that Congress sought through the parenthetical in Section 302(j) to shield sources of predominantly fugitive emissions because of the value of their product to the Nation or the relative harmlessness of their emissions. Although EPA recognizes that the *Alabama Power* opinion can be viewed as supporting this claim, it nevertheless is inclined to disagree with it. If Congress had intended to shield any sources at all for those reasons, it would not have distinguished between sources on the basis of whether their emissions are predominantly fugitive. There is simply no correlation between the value of a source's product or the harmfulness of the pollutants it emits, on the one hand, and the way those pollutants emanate, on the other. There are, moreover, many sources of predominantly non-fugitive emissions whose product Congress probably would have regarded as being as valuable as that of any source of predominantly fugitive emissions. Yet Congress did not seek to protect them.

EPA also has rejected preliminarily a fifth interpretation that surfaced recently. This interpretation is that the parenthetical in Section 302(j) merely requires EPA to identify those sources that are substantial emitters of fugitive emissions. The Natural Resources Defense Council and other environmental groups espoused this interpretation in a letter to EPA dated September 14, 1982, a copy of which appears in the docket for this rulemaking. EPA disagrees with the interpretation because it would make the parenthetical in Section 302(j) nearly pointless; under such a test the rulemaking that parenthetical clause calls for would add little to what is common knowledge anyway.

EPA solicits comment on the proper interpretation of Section 302(j) and, in particular, on which of the five interpretations outlined above is the strongest. Commenters should take into account a recent decision of the Court of Appeals for the D.C. Circuit, namely, *Duquesne Light Co. v. EPA*, 698 F.2d 456 (D.C. Cir. 1983). In that decision, the court upheld EPA's Section 302(j) rulemaking for inclusion of fugitive emissions in applicability determinations in EPA's noncompliance penalty regulations.

7. *Proposed Amendments.* In light of its new interpretations of Section 302(j), EPA has concluded preliminarily that it probably erred in requiring the inclusion

[11] EPA does not view Section 302(j) under either of these two interpretations as requiring it to state in regulatory form the operating mechanics of the methods of measurement, modeling or control upon which it relies in making a Section 302(j) determination. Nevertheless, any method that underlies a proposal to require inclusion would of course be fully disclosed and subject to the notice and comment process as part of the basic Section 302(j) listing proceeding.

of fugitive emissions in threshold applicability determinations for the 30 listed categories, since it did not identify any problems the sources in those categories would encounter in PSD and nonattainment review that are endemic to their fugitive emissions or determine that reasonable solutions for those problems exist. EPA, therefore, is here proposing amendments to the PSD and nonattainment regulations that would delete those requirements. Another purpose of those amendments is to fulfill the commitment EPA made to AMC in January 1981 to clarify that any project that would be "major" only if fugitive emissions were taken into account is not to be considered "major" for any PSD purpose, unless EPA has gone through the necessary rulemaking.

The amendments would add a new paragraph to the PSD and nonattainment definitions of "major stationary source" that would exclude from that category any source which would be "major" only if its fugitive emissions were counted, unless EPA has gone through the necessary rulemaking. Specifically, the new paragraph would provide that the "fugitive emissions of a stationary source shall not be included in determining for any of the purposes of [the regulations in question] whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved]." This formulation would have no effect on pollutant applicability determinations; fugitive emissions from a source that is "major" by virtue of its non-fugitive emissions would still have to be counted in any such determination.

The amendments would also add a similar paragraph to the PSD and nonattainment definition of "major modification." It would provide that "[a]ny net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of [the regulations in question] whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved]."

8. *Crediting of Decreases in Fugitive Emissions.* In general, the first step in determining whether a proposed physical change or change in method of operation at a plant amounts to a "major modification" for PSD or nonattainment purposes is to sum any increases and decreases in emissions that would result directly from the alteration at the unit or units subject to the alteration. If the sum of those increases and decreases is not "significant", then the alteration cannot be a "major modification." *See, e.g.*, 40 CFR 52.21(b)(2)(i), (b)(3)(i)(*a*) (1982); 45 FR 52698 (col. 3).[12] The second step is to sum any "creditable" [13] increases and decreases in emissions that will have occurred elsewhere at the plant contemporaneously with the alteration. *See, e.g.* , 40 CFR 52.21(b)(3)(i)(*b*). The final step is to total the sums from the first two steps. If the result equals or exceeds the relevant threshold, then the alteration is a "major modification"; otherwise, it is not.

The proposed amendment to the definitions of "major modification" would allow decreases in fugitive emissions to be included in both the first and second steps of a threshold applicability determination for a plant alteration, but only to the extent that the decreases exceeded any increases in fugitive emissions. The examples in the following footnote illustrate this point.[14]

EPA tentatively has concluded that the exclusion of decreases in fugitive emissions from threshold applicability determinations might be inconsistent with Congressional intent. For instance, the *CMA* settlement agreement contemplates the proposal of an amendment that would require both the first and second steps of a threshold applicability determination for a plant alteration to exclude any decreases, as well as increases, in fugitive emissions, unless EPA had gone through the necessary rulemaking.[15] That amendment, however, could result in a company having to obtain a permit, but not having to satisfy any substantive requirements, since the pollutant applicability determination would include all increases and decreases in fugitive emissions. For instance, in Examples C and D in the footnote the company would have to get a permit because non-fugitive emissions would total 50 tpy, but it would not have to satisfy any substantive requirements because the total of all increases and decreases would be less then zero. Since Congress could not have intended to create that possiblility, EPA has decided not to propose the provision contemplated by the settlement agreement or any provision like it.

Furthermore, under its tentative interpretation of the parenthetical in Section 302(j), EPA can see no reason to disallow credit for decreases in fugitive emissions in either the first or second steps of a threshold applicability determination for a plant alteration. The basic aim of Section 302(j) with respect to PSD and nonattainment new source review is to prevent increases in fugitive emissions from triggering applicability of the substantive PSD or nonattainment requirements until EPA has gone through the necessary rulemaking. Allowing credit for decreases in fugitive emissions, but disallowing it for an increase in fugitive emissions of the

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[12] On their face, the relevant definitions do not expressly state that an alteration must result by itself in a "significant" net increase in emissions in order to amount to a "major modification." EPA, however, has interpreted those definitions to provide as much. See Memorandum, Director, EPA Division of Stationary Source Enforcement, to Chief, Technical Analysis Section, EPA Region VII (January 22, 1981).

[13] Not all contemporaneous increases and decreases may be taken into account. The PSD and nonattainment regulations specify the precise increases and decreases that may be credited. *See, e.g.*, 40 CFR 52.21(b)(3)(iii)–(vi) (1982).

[14] *Example A.* Suppose that a company proposes an alteration to a unit at its plant that would cause: (1) Non-fugitive emissions of volatile organic compounds ("VOC") and (2) fugitive emissions of VOC from the unit to increase by 500 tpy. Suppose further that EPA has not gone through the necessary rulemaking to include fugitive emissions in threshold applicability determinations for the category of sources to which the plant belongs. Under the proposed amendment, the alteration would not amount to a "major modification," since the increase in fugitive emissions must be ignored and the "significance" level for VOC is 40 typ. *See, e.g.*, 40 CFR 52.21(b).

Example B. Suppose that the same company proposes a separate alteration at the same plant that would cause: (1) Non-fugitive VOC emissions from a unit to increase by 500 tpy and (2) fugitive VOC emissions from the unit to decrease by 475 tpy. Under the proposed amendment, the alteration would not amount to a "major modification," since the net increase in emissions from the alteration itself would be 25 tpy.

Example C. Suppose that the company proposes another alteration to its plant that would cause: (1) Non-fugitive VOC emissions from a unit to increase by 50 tpy, (2) fugitive VOC emissions from one portion of the unit to decrease by 25 tpy, and (3) fugitive VOC emissions from another portion to increase by 20 tpy. Under the proposed amendment, the alteration might amount to a "major modification," since it would result by itself in a 45 tpy net increase in non-fugitive VOC emissions. The net non-fugitive emissions, as explained earlier, are determined by subtracting any *net* decrease in fugitive emissions from the increase in non-fugitive emissions. Any contemporaneous and otherwise creditable changes in VOC emissions elsewhere at the plant would still have to be taken into account, however.

Example D. Suppose with respect to the alteration in Example C that the only contemporaneous and otherwise creditable change elsewhere at the plant was a decrease in fugitive emissions of 100 tpy. Under the proposed amendent, the alteration would not amount to a major modification, "since there would be no net increase in non-fugitive emissions.

Example E. Suppose that a creditable 100 tpy increase in fugitive VOC emissions occurred after the decrease in Example D, but before the alteration. Under the proposed amendment, the alteration then would amount to a "major modification."

[15] Specifically, the amendment, if it were promulgated, would add a paragraph to the definitions of "major modification" which would provide that "[i]ncreases and decreases in fugitive emissions shall not be included in determining for any of the purposes of this section whether a change at a stationary source would result in a significant net emissions increase, unless the source belongs to one of the following categories of stationary sources: [Reserved]."

same pollutant at the same plant, would not disserve that aim.

EPA recognizes that to credit net decreases in fugitive emissions, but not net increases, is at least superficially anomalous. For that reason, EPA requests close scrutiny of its analysis here and comment on whether any other pattern of crediting is justifiable.

9. Future Rulemaking on Fugitive Emissions. If EPA were to delete the current requirement for including fugitive emissions in threshold applicability determinations before it re-established that requirement through Section 302(j) rulemaking, some environmentally significant projects that would be subject to PSD or nonattainment new source review at present would escape that review entirely. To avoid this, EPA plans, if it is still inclined to delete the current requirement after reviewing comments that respond to this notice, to withhold final deletion until it completes the necessary rulemaking to re-establish the requirement as to at least some of the 30 categories presently listed. Specifically, if after reviewing the comments EPA still adheres to one of its two new interpretations, then its next step would be to propose one or more new listings on the basis of whatever advance findings that the new interpretation requires. The choice of interpretation, the findings and the new requirement would then all be subject to comment. Ultimately, EPA would formally adopt one interpretation, make the necessary findings, and promulgate the requirement.

EPA solicits comment on whether it should follow this plan of action and, if so, as to which sources it should withhold deletion.

B. Federal Enforceability

1. *Background.* As noted above, each of the five sets of PSD and nonattainment regulations aim their substantive requirements at new "major stationary sources." Each set defines "major stationary source" as any source that would have the "potential to emit" certain amounts of air pollutants. *E.g.*, 40 CFR 52.21(b)(1) (1982). Each then defines "potential to emit" as the maximum capacity of a stationary source to emit a pollutant under its physical and operational design," but adds that any limitation on the capacity of a source to emit a pollutant is to be treated as part of its design only if the limitation is federally enforceable". *E.g. id.* § 52.21(b)(4). The regulations define "federally enforceable" as "enforceable by the Administrator."*E.g., id.* § 52.21(b)(17). They add that the limitations that are "enforceable by the Administrator" include limitations contained in: (1) A SIP, (2) a construction permit issued under the SIP, (3) a standard of performance promulgated under Section 111 of the Act ("NSPS"), or (4) an emissions standard for hazardous pollutants promulgated under Section 112 ("NESHAPS"). *E.g., id.* In practice, EPA has declined so far to consider any other limitation as being "federally enforceable."

In effect, those definitions require one, in calculating the "potential to emit" of a proposed source for a particular pollutant, to assume that the source would emit the pollutant at the maxumum rate that the source could physically emit it, unless the source would be subject to a limitation on its operation that EPA could enforce directly. For example, suppose a company plans to operate a proposed source only 16 hours per day. Suppose further that the source would emit a particular pollutant in "major" amounts if it were operated 24 hours per day at its maximum physical capacity, but not if it were operated only 16 hours per day at that capacity. Under the definitions of "potential to emit" and "federal enforceability,"one must assume, notwithstanding the company's plans, that it would operate the source 24 hours per day, unless the company has established a specific prohibition against operation of the source in excess of 16 hours per day either in a SIP construction permit or in a SIP revision.

Each of the five sets of regulations also aims its substantive requirements at "major modifications," a term which, as described earlier, includes any "significant net emissions increase" at a major stationary source. The accounting system for determining such significant increases parallels the one described above for determining whether new sources exceed their own size thresholds.[16] *E.g., id.* § 52.21(b)(2). Specifically, the regulations define a "net emissions increase" as the amount by which the sum of (1) the increase in "actual" emissions from the proposed change and (2) any contemporaneous and otherwise creditable increases and decreases in "actual" emissions at the source would exceed zero. *E.g., id.* § 52.21(b)(3).

Since a proposed new unit at a source has yet to produce emissions, each set of regulations provides that the "actual" emissions of any such change equals its "potential to emit." *E.g., id.* § 52.21(b)(21)(iv). The definition of "potential to emit", as noted above, contains a requirement for federal enforceability . In addition, each set of regulations provides that the "actual" emissions of a unit may be presumed to equal any "source-specific allowable emissions" for the unit. *E.g., id.* § 52.21(b)(21)(iii). The definition of "allowable" emissions, like the definition of "potential to emit," is articulated in part in terms of federal enforceability. *E.g., id.*, § 52.21(b)(16). Finally, each of the regulations provides that a contemporaneous decrease in emissions is creditable only to the extent that it "is *federally enforceable* at and after the time that actual construction on the particular change begins. "*E.g., id.* § 52.21(b)(3)(vi)(*b*) (emphasis added).

2. *Industry Challenges to the Federal Enforceability Requirement.* Several parties have petitioned the D.C. Circuit in *CMA* to review the requirement for federal enforceability in the definitions of "potential to emit" and "net emissions increase." Some of them have also petitioned EPA to reconsider the requirement. They point out that in general each SIP already prohibits construction of a new "major stationary source" or "major modification" without a PSD or nonattainment permit. Accordingly, any company that builds a project that emits, or has the potential to emit, pollution in excess of the applicable thresholds without first obtaining a permit would be in violation of the law and therefore subject to enforcement action by EPA. For this reason, the petitioners assert, there is no need for EPA to require companies to obtain legal limitations that are separately enforceable by EPA in order to avoid the need for a PSD or nonattainment permit. The petitioners also pointed out that, to obtain the necessary limitation in a SIP construction permit or SIP revision, a company would have to apply to the state agency for the change and then await whatever public procedures and EPA scrutiny that were required. As a result, a company could experience substantial expense and delay just in obtaining the necessary limitation. *See* Fugitive Emissions Brief, at 50–53; AMC Petition for Reconsideration, at 32–34.

3. *EPA Reconsideration and Stay of the Requirement.* In July 1981, EPA announced that it had decided in response to those objections to reconsider the federal enforceability requirement and to formulate a

[16] For PSD purposes, pollutants subject to this review are (1) the pollutants for which a national ambient air quality standard ("NAAQS"), NSPS, or NESHAPS exists and (2) their precursors. *E.g.*, 40 CFR 52.21(b)(2)(i), (b)(23)(i) (1982). For nonattainment purposes, they are the pollutants for which a NAAQS exists and their precursors. *See* 45 FR 52711 (col. 3); *E.g.*, 40 CFR 51.18(j)(1) (x).

rulemaking proposal on the issue. 46 FR 36698 (July 15, 1981). In addition, the agency stayed the requirement for 90 days and solicited comment on whether to extend the stay. Subsequently, EPA stated that it did not plan to extend the stay. 46 FR 61613 n.1 (December 17, 1981).

4. *EPA Response to Industry Challenges.* EPA preliminarily agrees that the federal enforceability requirement is unnecessary to some extent and will consider deleting it. One of the purposes behind the requirement was to obtain corroboration, in the case of a new unit, that any voluntary limitation on its capacity to emit a pollutant is in fact part of its physical and operational design and, in the case of a modification, that the company in fact does intend to reduce actual emissions at the source in question. Another purpose was to assure that someone with strong enforcement capability had the legal and practical means of holding a company to its commitment. 45 FR 52701 (col. 3); *id.* at 52688 (col. 1 col. 2). EPA still adheres to those purposes. However, EPA now inclines to the view that a requirement for both enforceability by any federal, state or local governmental entity and discoverability by EPA and any other person would serve those purposes adequately. EPA has no reason to believe either: (1) That a company would take a limitation that is enforceable by a state or local agency any less seriously than it would take a limitation that is enforceable by EPA or (2) that the enforcement leverage of state and local governments is materially smaller than EPA's. EPA, moreover, would retain the ability to enforce the prohibition against construction without a permit that exists generally in each SIP.

5. *Proposed Amendments.* EPA, therefore, is proposing (1) to delete the word "federally" in the definitions of "potential to emit" and "net emissions increase" in the PSD and nonattainment regulations and (2) to put a definition of "enforceable" in place of the definition of "federally enforceable." "Enforceable" would be defined as "enforceable under federal, state or local law and discoverable by the Administrator and any other person." EPA would regard as "enforceable" under this definition not only the presently accepted terms in a SIP revision or SIP construction permit, but also any concrete limitation in an operating permit or non-SIP air pollution permit that is enforceable legally and practically under state or local law. EPA would regard as "discoverable" any enforceable limitation on emissions that is in writing, on file with the relevant permitting authority, and accessible to the public.

EPA is also proposing to delete the work "federally" in the definition of "allowable emissions," so that the allowable emissions of a source would be the lowest level allowed by any enforceable limit on operations, not just the lowest level allowed by federally enforceable limits. The regulations require the "allowable emissions" of a new project to be taken into account in assessing its impact on air equality. *E.g.*, 40 CFR 52.21(k) (1982). The primary purpose of this change is to ensure that any limitation on emissions that is enforceable by a state or local agency shall be included in that assessment. The regulations also allow credit for decreases in emissions under the definition of "net emissions increase" only to the extent that the "old level of actual emissions or the old level of *allowable emissions*, whichever is lower, exceeds the new level of actual emissions." *Id.* § 52.21(b)(3)(vi)(*a*) (emphasis added). Hence, another purpose of the change is to clarify that a limitation that is enforceable only by a state or local agency sets the baseline under that provision.

EPA is further proposing to amend the exemptions which appear in the definition of "major modification" for certain increases in hours of operation or production rate and for certain switches in fuel or raw material. The relevant provisions currently lift the exemption as to such an increase or switch if a "federally enforceable" condition established after a certain date in a SIP construction permit would bar the increase or switch. *E.g.*, 40 CFR 52.21(b)(2)(iii)(*e*) (*1*) and (*f*) (1982). The amendments EPA is proposing would also lift the exemption as to such an increase or switch whenever an "enforceable" condition established after the effective date of the amendments would bar the increase or switch. At least one purpose of the current provisions is to buttress limitations on such increases and switches in SIP construction permits by making such an increase or switch a violation not only of a permit, but also of the prohibition against construction without a permit in the relevant regulations. The proposed amendments would merely extend that purpose to any parallel limitations outside of SIPS and SIP construction permits.

6. Enforceability of External Offsets. Finally, EPA is proposing to delete the term "federally" in 40 CFR 51.18(j)(3)(ii)(*e*) (1982), which provides that "[a] 11 emission reductions claimed as offset credit [17] shall be federally enforceable," EPA sought through that provision to embody the last sentence of Section 173 of the Act, which provides that "[a]ny emission reductions required as a precondition of the issuance of a permit . . . shall be *legally binding* before such permit may be issued." 42 U.S.C. 7503 (emphasis added). The purpose of the proposed deletion is to establish that an emission reduction may be regarded as "legally binding" even if it is not embodied in a SIP revision or SIP construction permit. A limitation in a bare stipulation, however, could never make an emission reduction "legally binding," since the prohibition against construction without a permit would provide no enforcement leverage against a source that is not constructing itself but providing an offset that allows others to construct.

C. Health and Welfare Equivalence

1. *Background.*

As noted above, the five sets of PSD and nonattainment regulations define "major modification," roughly, as any change at a source that would result in a "signficant net emissions increase" in any one of certain pollutants. "Net emissions increase," in turn, is defined as the amount by which the sum of: (1) The increase in emissions from the proposed change, and (2) any creditable increases and decreases elsewhere at the source would exceed zero. *E.g.*, 40 CFR 52.21(b)(3)(i)(1982). The regulations restrict the creditability of some decreases in emissions. One provision, in particular, allows credit for a reduction only to the extent that it has approximately the same qualitative significance for public health and welfare as the increase from the proposed change. *E.g., id.* §52.21(b)(3)(vi)(*c*).

2. *Industry Challenge.* Several of the industry petitioners in *CMA* have challenged that restriction on the creditability of emission reductions. They contend primarily that EPA lacked authority to create the restriction. *See* Petitioner's Brief on Health and Welfare Equivalence Restriction Issue, at 30–34 (February 12, 1981).

3. *EPA Response.* In *Alabama Power*, the D.C. Circuit held that EPA may apply, and may obligate the states to apply, the PSD permit requirements to a proposed change at a source only if the

[17] A fundamental requirement of nonattainment new source review is, roughly, that the applicant show that its project would be accompanied by emission reductions elsewhere that would "offset" the relevant emissions from the project. *See, e.g.* Section 173(1), 42 U.S.C. 7503(1).

change amounts to a "modification" as defined in Section 111(a)(4a).[18] 636 F.2d at 399, 400–03. The court further held that a change at a source amounts to a "modification" only if, together with contemporaneous changes at the source, it would result *quantitatively* in a significant net increase in the emissions of the pollutant in question. *Id.* at 401. Hence, the court concluded that "[w]here there is no net increase from contemporaneous changes within a source, . . . PSD review, whether procedural of substantive, cannot apply." *Id. at 403.* That principle applies to the relevant nonattainment requirements as well, since the definition of "modification" for nonattainment purposes takes its content from Section 111(a)(4), too. *See* § 171(4), 42 U.S.C. 7501(4). Thus, EPA may not require the application of the PSD or nonattainment requirements to a change at a source, if the change, together with contemporaneous changes, would *not* result quantitatively in a net increase in emissions of the pollutant in question.

As the industry petitioners contend, however, EPA has violated that prohibition by restricting the creditability of a contemporaneous decrease in emissions according to the health and welfare significance of the decrease. Because of that qualitative restriction, the requirements of the PSD or nonattainment regulations could apply to a change at a source, even if a contemporaneous decrease in emissions would offset the increase from the change quantitatively.

While the Congress gave EPA considerable discretionary rulemaking powers under Section 301 to implement the Act, it did not intend that EPA develop qualitative tests which would be inconsistent with Section 111 (a)(4). Congress expressly gave EPA, not source applicants, the job of determining the effects of air pollution on public health and welfare. *See, e.g.* §§ 108, 109, 112, 42 U.S.C. 7408,7409, 7412. That job requires substantial time, money, manpower and scientific expertise. It is extremely unlikely that Congress intended to authorize EPA to require companies to perform that job on their own, particularly in the context of preconstruction review. In fact, there is absolutely no suggestion in the Act or its legislative history that Congress intended to complicate preconstruction review in that way. EPA does believe, however, that it has Section 301 rulemaking authority to create netting tests which act to limit the quantitative availability of certain emissions reductions *(e.g.* limit credit for decreases which are otherwise required by the SIP to make any of the required demonstrations relating to the attainment and maintenance of increments and standards). Thus, while the Agency would not develop a health and welfare equivalence criterion, it can restrict netting credit for a particular emissions reduction already required by the plan in order to avoid double counting of this decrease.

Finally, EPA has concluded preliminarily that, even if it had the authority to impose the restriction, the wording of it is unlawfully vague. It provides a prospective applicant with too little indication as to exactly what it must do.

4. *Proposed Amendments.* In view of these conclusions, EPA is proposing to delete the restriction as it currently appears in the PSD and nonattainment new source review regulations. EPA is also proposing, however, to add a new definitional provision that in general would exclude certain organic compounds from the term "volatile organic compounds" as that term is used in the PSD and nonattainment regulations.[19] The compounds are those that EPA has determined to be negligibly photochemically reactive and hence not precursors of ozone. *See* 42 FR 35314 (July 8, 1977); 44 FR 32043 (June 4, 1979); 45 FR 32424 (May 16, 1980); and 45 FR 48941 (July 22, 1980). They are, therefore, not pollutants which are "subject to regulation under the Act" within the meaning of the PSD and nonattainment regulations. The purpose of the proposed provision is to clarify that increases and decreases in emissions of those compounds are to be ignored completely in any applicability determination.

D. Definition of "Significance"

1. *Background.* In revising the PSD regulations in August 1980, EPA introduced provisions which use the term "significant." One of those provisions is the definition of "major modification," which, as noted above, defines that term as any change at a major stationary source that would result in a "significant net emissions increase" in any one of certain pollutants. The other provisions require an applicant for a PSD permit to meet certain requirements for control technology and air quality impact assessments for each pollutant regulated under the Act that the proposed project would emit in a "significant" amount. *E.g.*, 45 FR 52741 (§ 52.21(j)).

In revising the PSD regulations, EPA also introduced a definition of "significant." The first paragraph of that provision defines "significant" in terms of rates of emissions. For example, a rate of 40 tons per year or more is "significant" for sulfur dioxide; 25 tpy for particulate matter. *E.g.*, 45 FR 52737 (§ 52.21(b)(23)(i)). Another paragraph of the definition, however, provides:

> Notwithstanding [the first paragraph], "significant" means any emissions rate or any net emissions increase associated with a major modification which would construct within 10 kilometers of a Class I area and have an impact on such area equal to or greater than 1 ug/m³ (24-hour average). [*E.g.*, 45 FR 52739 (§ 52.21(b)(23)(iii)).]

2. *Industry Challenges.* In *CMA*, certain industry petitioners have challenged the paragraph quoted above. They contend that EPA, in promulgating it, violated Section 165(e)(3)(A) of the Act, which prohibits the agency from requiring "the use of any automatic or uniform buffer zone or zones" respecting the assessment an applicant must perform of existing air quality within the impact area of its proposed project. 42 U.S.C. 7475(e)(3)(A). *See* Fugitive Emissions Brief, at 54; AMC Petition for Reconsideration, at 35–36.

3. *EPA Response.* EPA agrees that this contention has some force. The threshold of one microgram per cubic meter effectively requires almost any company that would locate a project of significant size within 10 kilometers of a Class I area to perform an analysis of existing air quality for virtually each one of the pollutants regulated under the Act that the project would emit in significant amounts. Thus, the definition arguably creates a virtually uniform applicability zone respecting air quality analyses.

4. *Proposed Amendments.* As a result, EPA is proposing to delete the paragraph in question from both the Part 51 and Part 52 PSD regulations. EPA, however, is not proposing to substitute a new provision. The agency has no reason to believe at this time that the *de minimis* levels in the first paragraph do not provide adequate protection for Class I areas. EPA solicits comment on whether such reason exists and, if so, what new provision it should substitute in the event it decides to finally promulgate the requirement in the form proposed.

[18] Section 111(a)(4) provides that "modification" means "any physical change in, or change in the method of operation of, a stationary source *which increases the amount of any air pollutant emitted by such source* or which results in the emission of any air pollutnat not previously emitted. 42 U.S.C. 7411(a)(4) (emphasis added.)

[19] It would not exclude a compound if it were subject to an NSPS or NESHAP.

E. Innovative Control Technology Waiver

1. *Background and Industry Challenge.* In revising the PSD regulations in August 1980, EPA established for the first time a procedure for granting innovative control technology waivers of certain PSD requirements, which the agency patterned after the innovative control technology waiver in Section 111. *See* 45 FR 52735, 52741. The regulations, however, entirely disallow such a waiver if a proposed project would "impact any Class I area." *E.g.*, 40 CFR 52.21(v)(2)(iv)(*b*).

In *CMA*, certain industry petitioners, including AMC, challenge that disallowance provision. They contend primarily that the provision is arbitrary because it disallows the waiver even if an impact is "insignificant or temporary." Fugitive Emissions Brief, at 55.

2. *EPA Response.* EPA agrees preliminarily that the current formulation of the waiver is overly stringent with respect to Class I areas. Under the current PSD regulations, an applicant whose project would affect a Class I area can nevertheless get a PSD permit, if the applicant shows that the project would not cause or contribute to a violation of an increment for the area and the Federal Land Manager fails to show that the project would adversely impact any air quality related values of the area. *E.g.*, 40 CFR 52.21(p)(3) (1982). In fact, even an applicant whose project would *violate* a Class I increment might be able, nevertheless, to get a permit through special variance procedures in subsections (p)(4)–(7) of the regulations. In contrast, an applicant whose project under an innovative control technology waiver would merely *affect* a Class I area cannot get the waiver under any circumstances.

EPA, in creating this disallowance, sought to counterbalance an exemption that the waiver provision extends to applicants. Under subparagraph (v)(2)(iii), an applicant does not have to show that the proposed project would not cause or contribute to an increment violation while operating under the waiver. 45 FR 52727. As a result, but for the disallowance, a project under a waiver could violate a Class I increment or adversely affect an air quality related value. EPA agrees, however, that the waiver provision can be refined to exempt an applicant from providing most of the air quality impact analysis that it would otherwise have to provide with respect to the waiver period and still protect Class I areas fully.

3. *Proposed Amendments.* Hence, EPA is proposing to delete the current disallowance provision and to insert another provision that would allow the permitting authority to grant a waiver only if the provisions relating to Class I areas (*i.e.*, subsection (p)) have been satisfied with respect to *all* periods during the life of the source or modification. Obviously, this provision would expand the circumstances in which a waiver is available, but at the price of additional demonstrations for some applicants.

F. Secondary Emissions

1. *Background.* The 1978 version of the Part 52 PSD regulations provided in Section 52.21(l) that, to get a permit, an applicant had to show among other things, that the proposed project would neither cause nor contribute to a violation of a PSD increment or NAAQS. 43 FR 26407. The preamble to the regulations added that an applicant, in making that showing, generally had to include any quantifiable "secondary emissions" of the proposed project.[20] 43 FR 26403. The 1978 Part 51 PSD regulations echoed those requirements; it required any state PSD program to contain a provision equivalent to section 52.21(l). A definition of "secondary emissions" did not appear in the Part 51 or Part 52 regulations or in the preambles to them.

In revising the PSD regulations in August 1980, EPA retained, in the form of new Sections 52.21(k) and 51.24(k), the requirement for a demonstration that a proposed project would neither cause nor contribute to a violation of a PSD increment or NAAQS. 45 FR 52741, 52734. The agency, however, added a parenthetical to those provisions which expressly required the inclusion of "secondary emissions." It also put a definition of that term into both sets of regulations. Now, "secondary emissions" means:

> Emissions which would occur as a result of the construction or operation of a major stationary source or major modification, but do not come from the major stationary source or major modification itself. For the purpose of this section, secondary emissions must be specific, well defined, quantifiable and impact the same general area as the stationary source or modification. Secondary emissions include emissions from any offsite support facility which would not be constructed or increase its emissions except as a result of the construction or operation of the major stationary source or major modification. Secondary emissions do not include any emissions which come directly from a mobile source, such as emissions from the tailpipe of a motor vehicle, from a train, or from a vessel. [*E.g.*, 40 CFR 52.21(b)(18) (1981), as amended 47 FR 27554 (June 25, 1982).]

An example of an "offsite support facility" is a strip mine owned by one company that would be located next to a proposed power plant owned by another and that would supply only the power plant. Another example is a quarry owned by one company that would be located next to a proposed cement plant owned by another and that would supply only the cement plant.

2. *Industry Challenges.* In *CMA*, certain industry petitioners have challenged the requirement that an applicant must include "secondary emissions" in assessing air quality impacts for PSD purposes. They argue that EPA exceeded its authority in establishing the requirement. *See* Fugitive Emissions Brief, at 48–50; AMC Petition for Reconsideration, at 29–32. Specifically, they assert that the relevant statutory provision, section 165(a)(3), required an applicant to include only those emissions that would come directly from the proposed project, since the key language of that section refers only to the "emissions from the construction or operation *of such facility*."[21] 42 U.S.C. 7475(a)(3) (emphasis added).

3. *EPA Response.* EPA is inclined to conclude that a change in this requirement would be legally defensible, but it does not agree that an applicant need include only the emissions of its proposed project in its air quality impact assessment. Section 165(a)(3) also provides that an applicant must show that the proposed project "will not cause or *contribute* to, air pollution" in violation of a PSD increment or NAAQS. *Id.* (emphasis added). In order to determine whether a proposed project would contribute to a violation, one must take into account, not only the emissions from the project itself, but also the emissions from projects whose operation would coincide with it and whose emissions are reasonably quantifiable. Such projects are those

[20] In view of the restrictions on indirect source review in Section 110(a)(5) of the Act, the agency added that the applicant could ignore any "secondary emissions" from motor vehicles or aircraft. 43 FR 26403 n.9. EPA recently added vessels to that list, so that vessel emissions are now to be ignored as well. *See* 47 FR 27554 (June 25, 1982).

[21] Section 165(a) provides, in relevant part, as follows:

> (a) No major emitting facility on which construction is commenced after the date of the enactment of this part, may be constructed in any area to which this part applies unless—
>
> * * * * *
>
> (3) the owner or operator of such facility demonstrates that emissions from construction or operation of such facility will not cause, or contribute to, air pollution in excess of [42 U.S.C. 7475(a).]

which are already in operation or which, while not yet in operation, nevertheless have a construction permit. If those co-located and contemporaneous projects were ignored, it would be impossible to determine that the proposed project would not contribute to a violation of an increment or NAAQS.

While the "contribute" language thus persuades EPA that Congress intended the emissions from other projects to be taken into account, it does not persuade the agency that Congress also intended "secondary emissions" to be taken into account. Unlike the emissions from projects in operation or with permits, "secondary emissions" are arguably not reasonably quantifiable. The rate of emissions from an "offsite support facility" and their air quality impact will depend on a host of factors that will be largely unpredictable at the time an applicant is preparing its application. For a proposed strip mine, for instance, the probable unknowns will include the geographical distribution of haul roads, the type of digging equipment, the pattern of blasting, the number and size of hauling trucks, and the rate and method of coal extraction. EPA's current requirements appear to force a prospective applicant to assume the worst or attempt to prove that the "secondary emissions" in question are not reasonably quantifiable. The former approach may lead the applicant to impose constraints on the project artificially, not because of a reasonable prospect of real air quality degradation. The latter approach, on the other hand, may prove expensive and in the end fruitless. Congress arguably could not have intended to impose these burdens on applicants.

4. *Proposed Amendments.* As a result, EPA is proposing to delete the provisions in sections 51.24(k) and 52.21(k) which currently require the inclusion of "secondary emissions" in air quality impact assessments in PSD permit applications.[22] In addition, EPA is proposing to delete the second and last sentences in the PSD definition of "secondary emissions," since both would become superfluous with the exclusion of "secondary emissions" from such assessments. EPA is not proposing, however, to delete the definition altogether, since the PSD definition of "potential to emit" contains the useful clarification that "[s]econdary emissions do not count in determining the potential to emit of a stationary source." 40 CFR 51.24(b)(4), 52.21(b)(4) (1982).

EPA is also proposing deletions in the Offset Ruling that would parallel the proposed deletions in the PSD regulations. Finally, EPA is proposing to delete only the second and last sentence of the definition of "secondary emissions" in 40 CFR 51.18(j) and 52.24. Those two sets of nonattainment new source review regulations do not contain provisions that expressly require the inclusion of "secondary emissions" in air quality impact determinations.

G. Offset Credit for Source Shutdowns and Curtailments

1. *Background.* At the core of the Offset Ruling is the "offset" requirement: an applicant for a permit for a "major" project that would be located in an area that is nonattainment for a pollutant for which the project is major must show that the emissions of the pollutant from the project will be offset by sufficient creditable reductions in emissions elsewhere so as to assure reasonable further progress toward attainment and a net air quality benefit.[23] See 40 CFR Part 51, Appendix S, § IV.A. (1981).

The Ruling also contains elaborate rules for determining the creditability of emissions reductions. *Id.* § IV.C. One of those rules restricts the creditability of reductions that come from the permanent shutdown or curtailment of a source.[24] It provides in relevant part that a reduction from a shutdown or curtailment that occurred *before* the date of the application is creditable only if: (1) The shutdown or curtailment occurred after August 7, 1977 and (2) the proposed project is a replacement for the loss in productive capacity.[25] *Id.* § IV.C.3. n.9. The purpose of this restriction, according to EPA, was "to ensure that an offset relates to the current air quality problem . . . ." 44 FR 3280.[26]

The other EPA regulation governing nonattainment new source review—Section 51.18(j)—basically reflects the same "offset" requirement. *See* 40 CFR 51.18(j)(2) (1981) (referencing Section 173). Section 15.18(j) also contains elaborate rules for determining offset creditability, including one that imposes the same restrictions on reductions from pre-application shutdowns and curtailments that the Offset Ruling imposes. *Id.* §51.18(j)(3)(ii)(*c*).

2. *Industry Challenge.* In *CMA*, certain industry petitioners challenge the restriction in the Offset Ruling and Section 51.18(j) on the creditability of reductions from shutdowns and curtailments that occur before the date of application, but after August 7, 1977. they contend that EPA, by refusing to allow offset credit for such reductions except in the narrow circumstances of a replacement, has violated the intent of Congress and acted arbitrarily or capriciously. *See* Brief for Industry Petitioners on Source Shutdown and Curtailment (February 12, 1981).

3. *EPA Response.* EPA agrees preliminarily that the restriction in Section 51.18(j) contradicts Section 173. Section 173 provides that "[t]he permit program required [for nonattainment areas] *shall provide* that permits to construct and operate *may be issued*" if certain requirements are met, including an offset requirement. 42 U.S.C. 7503 (emphasis added). While this provision primarily tells each state that its SIP must contain a nonattainment permit program if it has a nonattainment area, it also tells EPA that it must approve any permit program that contains the requirements that Section 173 describes. *See Id.* § 7410(a)(2). The offset requirement that Section 173 describes would require an applicant to show only that sufficient emission reductions will have been obtained by the time the proposed project begins to operate so as to assure reasonable further progress toward attainment. *See* 42 U.S.C. 7503 (1) (A)–(B). As a result, an applicant could satisfy that requirement by pointing to reductions from pre-application shutdowns and curtailments that the state did not take into account in formulating its attainment strategy, *even if* the proposed project would not replace the lost productive capacity. By contrast, an applicant could satisfy the Section 51.18 requirement by pointing to such reductions, *only if* the proposed project would replace that capacity. Plainly, the Section 51.18 requirement would not recognize some of the shutdowns and curtailments that the Section 173 requirement would recognize. Section 51.18, therefore, purports to bar EPA from approving offset provisions that Section 173 requires it to approve. Thus, it contradicts Section 173.

EPA also agrees preliminarily that the restriction as it appears in the Offset

[22] It should be noted that this deletion would not affect the current rule that any actual increase in emissions at an offsite support facility which occurs after the applicable baseline date would consume increment. *E.g.*, 40 CFR 52.21(b)(13)(ii)*(b)* (1982).

[23] The Offset Ruling applies in only a few circumstances. In general, the construction moratorium, or preconstruction review programs approved as meeting the requirements of Section 173, have supplanted it.

[24] This provision appeared in the original Offset Ruling. 41 FR 55529 (December 21, 1976). EPA repromulgated it with some refinement when it revised the Ruling in January 1979. 44 FR 3284.

[25] This rule also provides that a reduction from a shutdown or curtailment that occurs *after* the date of application is creditable only if (1) the work force has been notified of the shutdown or curtailment and (2) the shutdown or curtailment is legally enforceable. *Id* § IV.C.3.

[26] In September 1980, EPA declined to revise the restriction in response to comments opposing it. *See* 45 FR 59876–77.

Ruling sets forth a rule that is undesirable. There arguably is no need to disallow offset credit for a reduction from a shutdown or curtailment so long as the reduction, together with any other reductions that the applicant may offer, would produce a net air quality benefit and reasonable progress toward attainment.

4. *Proposed Amendment.* In light of those conclusions, EPA is proposing to delete the challenged restriction from the relevant provisions in Section 51.18(j) and the Offset Ruling. EPA is also proposing to delete the restriction that relates to notification of the workforce. EPA can see no rational basis or authority for that restriction, since the notification has no bearing on air quality. Finally, EPA is proposing to change the dates in the current provisions from August 7, 1977 to "a reasonable date specified in the plan", in the case of Section 51.18, and to December 21, 1976 (the date of original promulgation of the Offset Ruling), in the case of the Ruling. The purpose of that change is to maximize the flexibility a permitting authority would have for granting offset credit. EPA specifically solicits comment, however, on whether there should be any time restrictions at all.

H. Banking of Offsets

The Offset Ruling contains a provision, subparagraph IV.C.5., which affirms that a permitting authority may give offset credit under the Ruling for past, "banked" reductions and which sets some boundaries on the circumstances under which it may grant this credit. The third and last sentences of that subparagraph also contain guidance on the approvability under Section 173 of a permit program that would give credit for "banked" offsets. Since adding that guidance to the Offset Ruling in January 1979, EPA has issued regulatory guidance on banking for purposes of nonattainment new source review in the form of Section 51.18(j) (3) and policy guidance in the form of the proposed Emissions Trading Policy, 47 FR 15076 (April 7, 1982). This newer guidance renders the guidance in the Offset Ruling superfluous. To avoid confusion, EPA is proposing here to delete the third and last sentences.

EPA currently is reconsidering other provisions that govern offset credit in the Offset Ruling and Section 51.18(j) in response to the objections to them raised by industry in *CMA* and in light of the proposed Emissions Trading Policy. EPA expects in the near future to propose amendments to those provisions.

III. Guidance

A. Obligation to Cure Increment Violations

EPA is currently reevaluating the NAAQS for particulate matter and expects to conduct rulemaking to revise it. EPA may propose not only new concentration levels for the NAAQS, but also in effect a new definition of "particulate matter" that would exclude particles above a size to be determined after further analysis of the relevant scientific information. The CMA settlement agreement specifies that when EPA proposes a new size cutoff for "particulate matter" for purposes of the NAAQS, it will also propose (1) a new size cutoff or PSD purposes that would remain in effect indefinitely (the "permanent PSD cutoff") and (2) an interim size cutoff for PSD purposes that would remain in effect until EPA takes final action on the permanent PSD cutoff.

Before EPA takes final action on the permanent PSD cutoff, one or more violations of a PSD increment for particulate matter may be discovered. If a violation of a PSD increment is discovered, the state has an obligation under 40 CFR 51.24(a)(3) (1981) to adopt such revisions to its SIP as would be necessary to cure the violation and to submit them to EPA for approval within 60 days afer discovery of the violation or within such longer period as EPA may determine after consultation with the state. In view of the possible promulgation of a new cutoff for particulate matter for purposes, EPA will postpone, until it takes final action on a permanent PSD cuttoff, the time by which a state must submit a SIP revision to cure a violation of an increment for particulate matter, if the state requests such a postponement. It should be noted, however, that the continued existence of an increment violation would pose a possibly insurmountable barrier to the issuance of a PSD permit to a project that would contribute to the violation.

B. Issuance of Non-PSD SIP Permits

SIPs contain a basic permit program that stands independent of any other permit program in the SIP and consist only of the requirements outlined by 40 CFR 51.18(a)-(i) (1982). Such a program would not contain any provisions relating to PSD increments. Under such a program the permitting authority may issue a permit even if modeling shows that the project in question would cause or contribute to a violation of a PSD increment for particulate matter or sulfur dioxide. Of course, if the project were subject independently to the PSD regulations in the SIP, it would have to have a PSD permit. To obtain a PSD permit, the owner or operator would have to show that the project would not cause or contribute to an increment violation.

C. Transfer of Technology for LAER

In revising the Offset Ruling in January 1979 and in providing guidance to the states for the preparation of SIP revisions to meet the requirements of Section 173, EPA stated that "in determining the lowest achievable emission rate (LAER), the reviewing authority may consider transfer of technology from one source type to another where such technology is applicable." 44 FR 3280' 44 FR 20379 (April 4, 1979). EPA interprets that statement as saying merely that the Agency would not disapprove a SIP revision that required technology transfer for LAER determinations. EPA was not attempting to say that it would approve a SIP revision which sought to incorporate the Section 173 requirements only if the revision required technology transfer. To the contrary, an express prohibition against technology transfer in the revision would not be grounds for disapproval.

IV. Miscellaneous

EPA solicits comment on the amendments it is proposing here. The initial period for the submission of written comment closes on October 11, 1983. EPA will not grant an extension of this initial comment period except upon an application showing some extraordinary cause. In the *CMA* settlement agreement, the agency committed to make good faith best efforts to take final action on the proposals here within 150 days from the date of this **Federal Register** notice. Any extension of the initial comment period would diminish EPA's ability to take final action within that period. EPA, in any event, currently plans not to extend the initial comment period beyond 60 days, since it committed not to do so in the settlement agreement. EPA will hold the public docket for this rulemaking open for 30 days after the close of the initial comment period for the submission of written rebuttal and supplementary information. All written comments and information should be submitted (in triplicate, if possible) to: Central Docket Section (A-130), Environmental Protection Agency, 401 M Street, S.W., Washington, D.C.20460. Attention: Docket A-82-23.

EPA has established a docket for this rulemaking, Docket No. A-82-32. The docket is an organized and complete file

of all significant information submitted to or otherwise considered by EPA during this proceeding. The contents of the docket will serve as the record in the case of judicial review under Section 307(b) of the Act, 42 U.S.C. 7607(b). The docket is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery I, 401 M Street, SW., Washington, D.C. A reasonable fee may be charged for copying.

EPA will hold a public hearing on the proposed amendments on September 29, 1983, at 10:00 a.m., in Room 5353, Waterside Mall, 401 M Street, SW., Washington, D.C. The hearing will be informal. A panel of EPA staff will hear the oral presentations. There will be no cross-examination and no requirement that any person be under oath. Each member of the panel may seek clarification or amplification of any presentation. The presiding officer of the panel may set a time limit for each presentation and may restrict any presentation that would be irrelevant or repetitious. A transcript of each hearing will be made and placed in the rulemaking docket.

Any person who wishes to speak at the hearing should as soon as possible send written notice of this to EPA, giving name, address, telephone number, and the length of the presentation. Anyone stating that his or her presentation would be longer than 20 minutes should also state why it need be longer. Each notice should be sent to Kirt Q. Cox, at the address given at the beginning of this notice. EPA will develop a schedule for presentations based on the notices it receives. Anyone who fails to submit a notice, but wishes nevertheless to speak at the hearing, should so notify the presiding officer immediately before the hearing. The presiding officer will decide whether, when, and for how long the person may speak. Each speaker should bring extra copies of his or her presentation for the convenience of the hearing panel, the hearing reporter, the press, and other participants. The hearings will be open to the public.

Under Exective Order 12291, EPA must judge whether an action it proposes to take would be a "major rule" and therefore subject to the requirement of a Regulatory Impact Analysis. The amendments EPA is proposing here would not constitute a "major rule," primarily because they would relieve current regulatory burdens.

The requirement for performing an economic impact assessment in Section 317 of the Act, s42 U.S.C. 7617, does not apply to the amendments EPA is proposing here. Section 317 applies only to "revisions which the Administrator determines to be substantial revisions." The proposed amendments are not substantial revisions, because they relieve current regulatory burdens and the Act requires them.

The proposed amendments have been submitted to the Office of Management and Budget for review under Executive Order 12291. Any comments from that office on the amendments and any EPA responses have been placed in the docket for this proceeding.

Pursuant to the provisions of 5 U.S.C. 605(b), EPA hereby certifies that the proposed amendments will not have a significant impact on small entities.

List of Subjects

40 CFR Part 51

Administrative practice and procedures, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Hydrocarbon, Carbon monoxide.

40 CFR Part 52

Air pollution control, Ozone, Sulfur oxides, Nitrogen dioxide, Lead, Particulate matter, Carbon monoxide, Hydrocarbons.

Authority: Sections 101(b)(1), 160–169, 171–178, and 301(a) of the Clean Air Act as amended (42 U.S.C. 7401(b)(1), 7410, 7470–79, 7501–08 and 7601(a)); section 129(a) of the Clean Air Act Amendments of 1977 (Pub. L. No. 95–95, 91 Stat. 685 (August 7, 1977)).

Dated: August 15, 1983.

Alvin L. Alm,

Deputy Administrator.

A. Requirements for State PSD Plans

§ 51.24 [Amended]

Section 51.24 of Title 40 of the Code of Federal Regulations, as amended at 47 FR 27554 (June 25, 1982), is proposed to be amended as follows:

1. By adding a new paragraph (b)(1)(iii) to read as follows: "(iii) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this section whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

2. By adding to paragraph (b)(2)(iii)(*e*)(*1*) an "(*i*)" after "prohibited" and the following clause just before the semicolon at the end of the paragraph: ", or (*ii*) under any enforceable condition which was established after [the effective date of this clause]";

3. By adding to paragraph (b)(2)(iii)(*f*) an "(*1*)" after "prohibited" and the following clause at the end of the paragraph: ", or (*2*) under any enforceable condition which was established after [the effective date of this clause].";

4. By adding a new paragraph (b)(2)(iv) to read as follows: "(iv) Any net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of this section whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

5. By deleting "federally" in paragraph (b)(3)(vi)(*b*), deleting the "; and" at the end of the paragraph, and putting a period in its place;

6. By deleting paragraph (b)(3)(vi)(*c*);

7. By deleting "federally" in the second sentence of paragraph (b)(4);

8. By deleting "federally" wherever it appears in paragraph (b)(16);

9. By revising paragraph (b)(17) to read as follows: "(17) 'Enforceable' means enforceable under federal, state or local law and discoverable by the Administrator and any other person.";

10. By deleting the second and last sentences of paragraph (b)(18);

11. By deleting paragraph (b)(23)(iii) [relating to Class I areas];

12. By adding a new paragraph (b) (29) to read as follows: "Volatile organic compounds' excludes each of the following compounds, unless the compound is subject to an emissions standard under Sections 111 or 112 of the Act: Methane; ethane; methylene chloride; 1,1,1trichloroethane (methyl chloroform); trichlorotrifluoroethane (CFC–113) (Freon 113); trichlorofluoromethane (CFC–11); dishlorodifluoromethane (CFC–12); chlorodifluoromethane (CFC–22); trifluormethane (FC–23); dichlorotetrafluoroethane (CFC–114); and chloropentafluoroethane (CFC–115).";

13. By deleting paragraph (i)(4)(ii) and redesignating paragraph (i)(4)(iii) as (i)(4)(ii);

14. By deleting the parenthetical in paragraph (k); and

15. By deleting paragraph (s)(2)(iv)(*b*), redesignating paragraph (s)(2)(iv)(*c*) as (s)(2)(iv)(*b*), and revising paragraph (s)(2)(v) to read as follows: "The provisions of subsection (p) of this section (relating to Class I areas) have been satisfied with respect to all periods

during the life of the source or modification.".

B. New Source Review for PSD Purposes

§ 52.21 [Amended]

Section 52.21 of Title 40 of the Code of Federal Regulations, as amended at 47 FR 27554 (June 25, 1982), is proposed to be amended as follows:

1. By adding a new paragraph (b)(1)(iii) to read as follows: "(iii) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this section whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

2. By adding to paragraph (b)(2)(iii)(*e*)(*1*) an "(*i*)" after "prohibited" and the following clause just before the semicolon at the end of the paragraph: ",or (*ii*) under any enforceable condition which was established after [the effective date of this clause]";

3. By adding to paragraph (b)(2)(iii)(*f*) an "(*1*)" after "prohibited" and the following clause at the end of the subparagraph: ", or (*2*) under any enforceable condition which was established after [the effective date of this clause].";

4. By adding a new paragraph (b)(2)(iv) to read as follows: "(iv) Any net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of this section whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved].":

5. By deleting "federally" in paragraph (b)(3)(vi)(*b*), deleting the "; and" at the end of the paragraph, and putting a period in its place;

6. By deleting paragraph (b)(3)(vi)(*c*);

7. By deleting "federally" in the second sentence of paragraph (b)(4);

8. By deleting "federally" wherever it appears in paragraph (b)(16);

9. By revising paragraph (b)(17) to read as follows: "(17) 'Enforceable' means enforceable under federal, state or local law and discoverable by the Administrator and any other person.";

10. By deleting the second and last sentences of paragraph (b)(18);

11. By deleting subparagraph (b)(23)(iii) [relating to Class I areas];

12. By adding a new paragraph (b)(29) to read as follows: " 'Volatile organic compounds' excludes each of the following compounds, unless the compound is subject to an emissions standard under Sections 111 or 112 of the Act: methane; ethane; methylene chloride; 1,1,1 – tricholoroethane (methyl chloroform); trichlorotrifluoroethane (CFC–113) (Freon 113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (CFC–22); trifluoromethane (FC–23); dichlorotetrafluoroethane (CFC–114); and chloropentafluoroethane (CFC–115).";

13. By deleting paragraph (i)(4)(vii) and redesignating paragraph (i)(4)(viii) as (i)(4)(vii);

14. By deleting the parenthetical in paragraph (k); and

15. By deleting paragraph (v)(2)(iv)(*b*), redesignating paragraph (v)(2)(iv)(*c*) as (v)(2)(iv)(*b*), and revising paragraph (v)(2)(v) to read as follows: "The provisions of paragraph (p) of this section (relating to Class I areas) have been satisfied with respect to all periods during the life of the source or modification.".

C. State Plans for New Source Review for Nonattainment Purposes

§ 51.18 [Amended]

Section 51.18 of Title 40 of the Code of Federal Regulations, as amended at 46 FR 50766 (October 14, 1981) and 47 FR 27554 June 25, 1982), is proposed to be amended as follow:

1. By deleting "federally" in the second sentence of subparagraph (j)(1)(iii);

2. By adding a new paragraph (j)(1)(iv)(*c*) to read as follows: "(*c*) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this subsection whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

3. By adding to paragraph (j)(1)(v)(*c*)(*5*)(*i*) an "(*A*)" after "prohibited" and the following clause just before the semicolon at the end of the paragraph: ", or (*B*) under any enforceable condition which was established after [the effective date of this clause]";

4. By adding to paragraph (j)(1)(v)(*c*)(*6*) an "(*i*)" after "prohibited" and the following clause at the end of the subparagraph: ", or (ii) under any enforceable condition which was established after [the effective date of this clause].";

5. By adding a new paragraph (j)(1)(v)(*d*) to read as follows: "(*d*) Any net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of this subsection whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

6. By deleting "federally" in paragraph (j)(1)(vi)(*e*)(*2*);

7. By deleting paragraph (j)(1)(vi)(*e*)(*4*);

8. By deleting the second and last sentences in paragraph (j)(1)(viii);

9. By deleting "federally" wherever it appears in paragraph (j)(1)(xi);

10. By revising paragraph (j)(1)(xiv) to read as follows: "(xiv) 'Enforceable' means enforceable under federal, state or local law and discoverable by the Administrator and any other person.";

11. By adding a new paragraph (j)(1)(xix) to read as follows: " 'Volatile organic compounds' excludes: methane; ethane; methylene chloride; 1,1,1-tricholoroethane (methyl chloroform); trichlorotrifluoroethane (CFC–113) (Freon 113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (CFC–22); trifluoromethane (FC–23); dichlorotetrafluoroethane (CFC–114); and chloropentafluoroethane (CFC–155).";

12. By revising paragraph (j)(3)(ii)(*c*) to read as follows: "(*c*) Emissions reductions achieved by shutting down an existing source or permanently curtailing production or operating hours below baseline levels may be credited, provided that the shutdown or curtailment occurred after a reasonable date specified in the plan.";

13. By deleting "federally" from paragraph (j)(3)(ii)(*e*); and

14. By deleting paragraph (j)(4) and renumbering paragraph (j)(5) as (j)(4).

D. Emission Offset Interpretative Ruling

Appendix S

Appendix S of Part 51 of Title 40 of the Code of Federal Regulations, as amended at 46 FR 50766 (October 14, 1981) and 47 FR 27554 (June 25, 1982), is proposed to be amended as follows:

1. By deleting "federally" in the second sentence of subparagraph II.A.3;

2. By adding a new paragraph II.A.4(iii)to read as follows: "(iii) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this Ruling whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

3. By adding to paragraph II.A.5(iii)(*e*)(*1*) an "(*i*)" after "prohibited" and the following clause just before the semicolon at the end of the

subparagraph: ", or (ii) under any enforceable condition which was established after [the effective date of this clause]";

4. By adding to paragraph II.A.5(iii)(*f*) an"(*1*)" after "prohibited" and the following clause at the end of the paragraph: ", or (*2*) under any enforceable condition which was established after [the effective date of this clause].";

5. By adding a new paragraph II.A.5(iv) to read as follows: "(iv) Any net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of this Ruling whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

6. By deleting "federally" in paragraph II.A.6(v)(*b*);

7. By deleting the "; and" in paragraph II.A.6(v)(*c*) and putting a period in its place;

8. By deleting paragraph II.A.6(v)(*d*);

9. By deleting the second and last sentences of paragraph II.A.8.;

10. By deleting "federally" wherever it appears in paragraph II.A.11.;

11. By revising paragraph II.A.12. to read as follows: "(12) 'Enforceable' means enforceable under federal, state or local law and discoverable by the Administrator and any other person.";

12. By adding a new paragraph II.A.20. to read as follows: " 'Volatile organic compounds' excludes: methane; ethane; methylene chloride; 1,1,1-tricholoroethane (methyl chloroform); trichlorotrifluoroethane (CFC–113) (Freon 113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (CFC–22); trifluoromethane (FC–23); dichlorotetrafluoroethane (CFC–114; and chloropentafluoroethane (CFC–115).";

13. By deleting paragraphs II.D.—II.G.;

14. By revising paragraph IV.C.3. to read as follows: "3. *Operating hours and source shutdown.* A source may be credited with emissions reductions achieved by shutting down an existing source of permanently curtailing production or operating hours below baseline levels (see initial discussion to this Section C), provided that the shutdown or curtailment occurred after December 21, 1976. Emission offsets that involve reducing operating hours or production or source shutdowns must be legally enforceable, as in the case for all emission offset situations.";

15. By deleting footnote 9; and

16. By deleting the third and last sentences of paragraph IV.C.5.

E. Restrictions on Construction for Nonattainment Areas

§ 52.24 [Amended]

Section 52.24 of Title 40 of the Code of Federal Regulations, as amended at 46 FR 50766 (October 14, 1981) and 47 FR 27554 (June 25, 1982), is proposed to be amended as follows:

1. By deleting "federally" in the second sentence of paragraph (f)(3f);

2. By adding a new paragraph (f)(4)(iii) to read as follows: "(iii) The fugitive emissions of a stationary source shall not be included in determining for any of the purposes of this section whether it is a major stationary source, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

3. By adding to paragraph (f)(5)(iii)(*e*)(*1*) an "(*i*)" after "prohibited" and the following clause just before the semi-colon at the end of the paragraph: ", or (*ii*) under any enforceable condition which was established after [the effective date of this clause]";

4. By adding to paragraph (f)(5)(iii)(*f*) an "(*1*)" after "prohibited" and the following clause at the end of the paragraph: ", or (*2*) under any enforceable condition which was established after [the effective date of this clause].";

5. By adding a new paragraph (f)(5)(iv) to read as follows: "(iv) Any net increase in fugitive emissions from a change at a stationary source shall not be included in determining for any of the purposes of this section whether the change is a major modification, unless the source belongs to one of the following categories of stationary sources: [Reserved].";

6. By deleting "federally" in paragraph (f)(6)(v)(*b*);

7. By deleting paragraph (f)(6)(v)(*d*);

8. By deleting the second and last sentences in paragraph (f)(8);

9. By deleting "federally" wherever it appears in paragraph (f)(11);

10. By revising paragraph (f)(12) to read as follows: "(12) 'Enforceable' means enforceable under federal, state or local law and discoverable by the Administrator and any other person.";

11. By adding a new paragraph (f)(18) to read as follows: " 'Volatile organic compounds' excludes: methane; ethane; methylene chloride; 1,1,1-trichloroethane (methyl chloroform); trichlorotrifluoroethane (CFC–113) (Freon 113); trichlorofluoromethane (CFC–11); dichlorodifluoromethane (CFC–12); chlorodifluoromethane (CFC–22); trifluoromethane (FC–23); dichlorotetrafluoroethane (CFC–114); and chloropentafluoroethane (CFC–115).";; and

12. By deleting paragraph (h) and renumbering the succeeding subsections accordingly.

[FR Doc. 83–23297 Filed 8–24–83; 8:45 am]

BILLING CODE 6560–50–M

federal register

Thursday
August 25, 1983

Part VI

Department of Health and Human Services

Public Health Service

Proposed Regulations on Confidentiality of Alcohol and Drug Abuse Patient Records

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

42 CFR Part 2

Confidentiality of Alcohol and Drug Abuse Patient Records

AGENCY: Public Health Service, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes editorial and substantive changes in the "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations. This proposal was prompted by the Department's commitment to make its regulations more understandable and less burdensome. The proposal clarifies and shortens the regulations and the proposed substantive changes will ease the burden of compliance.

DATES: Comments must be received on or before October 24, 1983.

ADDRESS: Submit written comments to: Judith T. Galloway, Legal Assistant, Alcohol, Drug Abuse, and Mental Health Administration, Room 13C-06, Parklawn Building, 5600 Fishers Lane, Rockville, Maryland 20857. Comments will be available for public inspection at this location between the hours of 9:00 a.m. and 4:00 p.m., Monday through Friday, except for Federal holidays.

FOR FURTHER INFORMATION CONTACT: Judith T. Galloway (301) 443-3200.

SUPPLEMENTARY INFORMATION: The "Confidentiality of Alcohol and Drug Abuse Patient Records" regulations, 42 CFR Part 2, were promulgated on July 1, 1975 (40 FR 27802) and became effective August 1, 1975. The regulations implement two Federal statutes applicable, respectively, to alcohol abuse patient records (42 U.S.C. 290dd-3) and drug abuse patient records (42 U.S.C. 290ee-3).

Prompted by its experiences in interpreting and implementing the confidentiality regulations the Department of Health and Human Services on January 2, 1980 published a notice in the **Federal Register** (45 FR 53) announcing its intention to make editorial and substantive changes in the regulations. The notice invited public comment on fifteen substantive issues and on any other substantive or editorial aspect of the regulations. Approximately 450 comments were received in response to the notice.

Summary of Proposed Changes

Editorial Changes

The regulations would be substantially shortened by the following editorial changes: (1) Deletion of all "Basis and Purpose" sections, those explanatory sections which follow each substantive section of the current regulations; (2) deletion of §§ 2.3 and 2.5, a reference to previous regulations and discussion of format which are no longer needed; (3) deletion of § 2.22, a section on former employees which is legally unnecessary; and (4) the combining of other sections. In addition each of the sections would be rewritten for clarity and conciseness.

Substantive Changes

The following major substantive changes are proposed: (1) Limitation of the applicability of the regulations to federally assisted programs specializing in the diagnosis, treatment or referral for treatment of alcohol or drug abuse patients; (2) a new requirement that programs give notice to each patient of the applicability and effect of the Federal confidentiality regulations; (3) the setting forth of a sample written consent form; (4) the elimination of the impediment in the regulations to a patient's access to his or her own records; (5) the elimination of those sections governing disclosures with written consent in specific circumstances, other than disclosures to central registries and in connection with criminal justice referrals, in favor of a section which permits any disclosure to which the patient has consented by signing the required written statement; and (6) elimination of the prohibition on the entry of a court order authorizing the disclosure of subjective information regarding a patient.

These and other proposed changes in the regulations are reviewed in detail in the discussion which follows.

Substantive Issues Listed in the Notice of Decision To Develop Regulations

(a) Should the regulations be amended to permit patient access to his or her records for the purpose of making copies and disclosures as the patient sees fit?

The 174 affirmative responses[1] were justified on grounds that the patient has a "right" to access, that access will permit a truly informed consent to disclose information, that access will facilitiate correction of erroneous records, and that access will encourage more accurate recordkeeping practices. Many of the affirmative responses were qualified. They favored access but only if treatment has been completed, the program retains discretion to prevent access, the staff can review the record and partially limit the disclosure, or if the patient has access only to objective data.

Negative responses [1] totaled 290. Those responses were justified on grounds that clinical discretion in permitting access is vital to the patient's well-being, that patient access would interfere with treatment or be harmful to the patient, that the patient would use poor judgment in disclosing the record to third parties, that patient access would result in censored or inaccurate recordkeeping, and that patient access would create an additional administrative burden on the program.

Section 2.23 of the proposed regulations states that the regulations do not prohibit giving a patient access to his or her records, including the opportunity to inspect and copy any records that the program maintains about the patient. It also provides that written consent or other authorization is not required by these regulations for such access. This proposed change in the current regulations reflects the trend toward a right of patient access to medical records and is based upon experience under the access provisions of the Privacy Act (5 U.S.C. 552a) indicating that patient access to medical records has not proved harmful. A number of States have statutes providing for direct patient access to physician or hospital medical records and access is guaranteed by case law in other States. On the Federal level the Privacy Act of 1974 required direct access under most circumstances and the Privacy Protection Study Commission, established under that Act has recommended that:

> [U]pon request, an individual who is the subject of a medical record maintained by a medical-care provider, or another responsible person designated by the individual, [should] be allowed . . . access to the medical record including an opportunity to see and copy it. "Personal Privacy in an Information Society, The Report of the Privacy Protection Study Commission" 298 (July 1977).

The purpose of the proposed change is not to grant a patient right of access but only to provide that the regulations do not restrict such a right of access. Consistent with the conclusion of the Privacy Protection Study Commission that no solution to the problem of patient access is acceptable so long as it risks leaving the ultimate discretion to release or not to release in the hands of

[1] The affirmative and negative categories for the public comments on the fifteen issues listed in the Notice of Decision To Develop Regulations are not precise measures because of the difficulty in categorizing qualified responses as either affirmative or negative. Furthermore, the total of the comments on a particular issue do not necessarily reflect the total number of those submitting comments, because some commenters did not respond to each issue and others made more than one response to certain issues.

the patient's physician (Report at 297), the proposed change would keep the confidentiality regulations from being cited as a legal basis for such an exercise of discretion by alcohol and drug abuse programs.

(b) Should the regulations be amended to require that a program give notice to each patient of the existence and effect of Federal law and regulations which protect the confidentiality of alcohol and durg abuse patient records? Should the notice requirement be extended to any applicable State laws and regulations on confidentiality?

Affirmative responses totaled 318. Those responses were justified primarily on grounds that patients have a "right" to know about laws that affect them and that patient knowledge of these laws will strengthen the therapeutic relationship. Many of the affirmative responses were qualified. They dealt with whether the notice should be limited to the Federal alcohol and drug abuse confidentiality requirements, the content of the notice to the patient, and with how the notice should be delivered.

Negative responses totaled 92. Many of those responses were justified on grounds that notice is unnecessary because current regulations permit notice if a program wishes to inform patients, and that requiring a notice in every case would be too expensive and time consuming. Some were against a notice requirement because it would confuse patients. Others feared a notice requirement would lead to additional litigation for failure to notify.

A new § 2.22 has been added requiring that the patient be notified of the existence and effect of the Federal statutes and regulations which protect the confidentiality of alcohol and drug abuse patient records. No requirement for notification of the existence and effect of State law is proposed, as this is considered to be a matter of concern primarily to each State. Of course, each program is free to notify patients of any applicable State law and any program policy concerning confidentiality not inconsistent with Federal or State law.

The proposed regulations require that when a patient is admitted (or as soon after as the patient is capable of rational communication) that the patient be told of the existence and effect of the Federal statutes and regulations protecting the confidentiality of alcohol and drug abuse patient records and that the patient be given a notice in writing. A sample notice is included in the text of the regulations to assist programs in complying with the notification requirement.

Notice to each patient at the outset that the program must maintain the confidentiality of patient records will provide an incentive for the patient to be frank and open in the therapeutic relationship. By stating the limits on the confidentiality protections, the notice will lessen the potential for subsequent misunderstandings and may deter criminal acts on program premises or against program personnel, since no confidentiality protections are afforded in that instance.

A disadvantage of this approach is that it will require additional paperwork: namely, written notice to the patient. The Department believes a written notice is the most effective, reliable means of informing patients of the confidentiality protections for alcohol and drug abuse patient records. The sample notice is included in the proposed regulations as an aid to compliance with the regulations and not as a required form. What is required is that the elements described in § 2.22(b) be communicated to each patient. Communication of the information in the sample form would accomplish that purpose, but a program may communicate the required information in any manner that will provide each patient with written notice of the elements in § 2.22(b).

(c) Should the regulations be amended to apply only to specialized alcohol or drug abuse treatment and rehabilitation programs?

Affirmative responses totaled 178. The most frequent justification for applying the regulations only to specialized programs was that the regulations are costly, time consuming and confusing for application by general medical care facilities, some of which deal with small numbers of alcohol and drug abuse patients. Some responses indicated that application of the regulations to general medical care facilities is unnecessary because those facilities generally abide by some standard of confidentiality already, for example, a standard imposed by State law.

Negative responses totaled 205. The most frequent justification for a broad application of the regulations was that drug and alcohol abuse patient records are sensitive and should be protected regardless of the nature of the provider. Some commenters suggested confusion would result from trying to distinguish "specialized" programs from general medical care facilities.

Under § 2.12 of the proposed regulations and the proposed new definition of the term "program" the confidentiality restrictions would apply only to alcohol or drug abuse patient records maintained by federally assisted individuals or organizational entities which "specialize" in alcohol or drug abuse referral, treatment, or diagnosis for referral or treatment by holding themselves out as providers of one or more of those services. Thus, for example, the confidentiality protections would apply to an alcohol or drug abuse treatment unit within a general hospital but, in the absence of specialized personnel, would not apply to alcohol or drug abuse treatment provided in a hospital emergency room or a general hospital ward.

It is believed that the proposed change will: (1) Simplify administration of the regulations without significantly affecting the incentive to seek treatment provided by the confidentiality protections, and (2) lessen the adverse economic impact of the current regulations on a substantial number of small entities. In enacting the drug abuse confidentiality statute Congress stated that the purpose of the confidentiality protections was to encourage entry into treatment by ensuring that the records of treatment would not be publicly disclosed. Given the short-term, emergency (sometimes involuntary) nature of much of the alcohol and drug abuse treatment provided by hospital emergency rooms and other providers which do not "specialize" in the care of alcohol or drug abusers, it is questionable whether the application of the confidentiality protections to these providers has any significant effect on the decision to seek treatment. Furthermore, it is questionable whether this brief, episodic treatment is the type of treatment that Congress intended to encourage through enactment of the confidentiality regulations.

The proposed limitation on the current broad applicability of the regulations will lessen the costs of compliance. These costs are greater for general medical care providers because of the difficulties in determining the applicability of the confidentiality restrictions to the records of a patient who is treated for ailments in addition to alcohol or drug abuse or ailments which have a causal relationship to the alcohol or drug abuse.

(d) Should the regulations be amended to permit an auditor or program evaluator to redisclose patient identifying information obtained from a referring program for the purpose of evaluating that program's client referral mechanism?

Affirmative responses totaled 59. The justification most often given was that facilitating audit and evaluation of the patient referral mechanism will enhance program quality. Other affirmative responses were qualified, urging that

any redisclosure by an auditor or program evaluator for the purpose of evaluating the patient referral mechanism be accompanied by safeguards against redisclosure.

The most frequent rationale among the 224 negative responses was that permitting redisclosure of patient identifying information by auditors/evaluators for the purpose of evaluating a program's referral mechanism would result in a breach of confidentiality and loss of program credibility. Other negative responses indicated that disclosure of patient identity is not necessary to assess the effectiveness of a program's client referral mechanism. Some commenters suggested that patient consent be obtained before an auditor/evaluator rediscloses patient identifying information.

The proposed regulations do not alter the present prohibition on redisclosure by auditor/evaluators. An auditor/evaluator may use patient identifying information only to carry out an audit or evaluation purpose or to investigate or prosecute the program for criminal activities, as authorized by a court order entered under § 2.65, and may not disclose that information except back to the program from which it was obtained. These restrictions are consistent with the statutory provisions governing the redisclosure of patient identifying information by auditors and evaluators and provide a simple means of insuring the confidentiality of patient identifying information which is disclosed to auditors or evaluators.

It has been suggested that these restrictions on redisclosure make it impossible to conduct an adequate evaluation of a program's patient referral mechanism. It appears that this criticism is based upon a misunderstanding of what constitutes "patient identifying information" and of the effect of the regulatory restrictions upon those programs to which a patient has been referred. As is made clear by the proposed definitions in § 2.11 of "disclosure," "Patient" and "patient identifying information" and the proposed § 2.13(c), the regulations do not restrict a communication of information which does not identify a named individual as an alcohol or drug abuser or a recipient of alcohol or drug abuse services. Thus, there is no restriction on an auditor inquiring of a facility to which a patient has been referred, "Was John Doe admitted for treatment or services on or about [a certain date]?" if that inquiry does not in any way identify the individual as an alcohol or drug abuser or a recipient of alcohol or drug abuse services. Since the statutes and § 2.53 of the proposed regulations (§ 2.52 of the current regulations) permit disclosures without patient consent for audit and evaluation activities the program is permitted to provide patient identifying information in response to the auditor's inquiry. Thus, if the auditor's inquiry can be made without identifying an individual as an alcohol or drug abuser or a recipient of alcohol or drug abuse services, current regulations permit evaluation of a program's referral mechanism.

(e) Should the regulations be amended to permit a patient to consent to disclosure of information by means of a more general consent form?

The 153 affirmative responses stated that a more general consent form would provide flexibility and convenience and be more likely to conform with State requirements, with State hospital association guidelines, or with the form used for all other patients of a facility. It was also stated that a general, unqualified consent to disclosure given when the patient is admitted allows the facility to make a disclosure without having to recontact a patient who has left treatment to obtain a consent for a particular purpose, perhaps unforeseen at the time of admission. Some general medical care facilities were concerned that the use of a special form for alcohol and drug abuse patients calls attention to them.

Negative responses totaled 240. Many respondents expressed satisfaction with the required elements for written consent and some suggested adoption of the format for all patients. A frequent justification for the retention of the specific requirements in § 2.31 was that they inform the patient specifically of what he or she is consenting to have disclosed. Others preferred retention of the present consent requirements because a more general form would lead to the release of additional, unnecessary, or unrequested information.

The proposed regulations retain the present requirement for a specific written consent. Section 2.31 has been changed only for editorial purposes and to add a sample consent form to aid programs in tailoring their consent forms to the requirements of § 2.31.

The primary advantage of retaining the specific elements required by § 2.31 is that of providing each patient with specific information on the disclosures that he or she is consenting to and thereby providing each patient with a greater degree of control over the disclosures. The report of the Privacy Protection Study Commission supports the Department's position and recommends the requirements of § 2.31 as a model for consent forms relating to all medical records.

The primary disadvantage of requiring that each written consent contain all the elements in § 2.31 is that it may be difficult for a general medical care facility to obtain a consent conforming to § 2.31 where a patient is initially admitted for a problem unrelated to alcohol or drug abuse, but is later treated, diagnosed, or referred for treatment for alcohol or drug abuse.

The Department believes these difficulties are minimized, if not eliminated, by the proposed limitation of the regulations to programs specializing in the provision of alcohol or drug abuse treatment or referral for treatment, or diagnosis for these purposes. These programs should be able to readily obtain a conforming consent prior to treating a patient for alcohol or drug abuse.

(f) Should the regulations be amended to facilitate reimbursement by making the written consent requirements less stringent for disclosures to third party payers and funding sources?

Affirmative responses totaled 165. These responses emphasized that the failure to obtain a consent conforming to § 2.31 (either because the patient chooses not to consent or because the program is unable to locate the patient) results in increased costs to all patients flowing from the program's inability to be reimbursed by a third party payer. Some responses were qualified: they favored less stringent consent requirements for third party payers but only if the third party payers were prohibited from redisclosing the information without getting the patient's consent.

Negative responses totaled 179. These responses indicated that the present requirements do not present an unreasonable burden in obtaining reimbursement from third party payers. Some also expressed a lack of confidence in the standards of confidentiality maintained by third party payers, making "informed consent" to release information an important goal.

The proposed regulations continue in effect the requirement for a § 2.31 written consent in making disclosures to a third party payer because the Department does not believe the requirement is unduly burdensome and because there is insufficient justification for treating third party payers differently from other recipients of disclosure. However it is noted that other changes in Subpart C will simplify all disclosures

with patient consent because the standard for permitting release of information with patient consent will be constant: the presence of each element required for consent under § 2.31 and a determination that the information disclosed is necessary to carry out the purpose for which the consent was given.

(g) Should the regulations be amended to extend to family members the liberal disclosure provision allowed for a patient's legal counsel?

Affirmative responses totaled 101. Some favored extension of the "short form" written consent procedures in § 2.35 of the current regulations to family members because it would be helpful to the patient's therapy. Others believed that if a patient is given access to his or her own records (see issue (a)) the patient should be able to give a general "short form" consent to a disclosure to any person, including family members. Others felt that only immediate family members or family members involved in the patient's treatment should be able to receive patient information pursuant to such a consent.

Negative responses totaled 228. Some were against this change because they believe an attorney's responsibility toward a client and a family's relationship with the patient are not comparable: The attorney is bound by professional ethics to act in the patient's best interest and has a "need to know" whereas the family lacks objectivity and may even be a part of the patient's problem. A few responses did not favor special procedures for lawyers or family but urged uniformity in the process for disclosing any information with patient consent.

The proposed regulations eliminate the need for consideration of this issue by deleting § 2.35 of the current regulations and establishing a uniform process for disclosures with written consent. The proposed §§ 2.31 and 2.33 would permit any disclosure to which the patient has consented by signing a written statement as required by the regulations, with special rules being retained only for disclosures to central registries and disclosures in connection with criminal justice referrals.

(h) Should there be any prohibition on redisclosure by the recipient of a disclosure made with written patient consent?

Affirmative responses totaled 278. Almost half of these responses were without comment or indicated satisfaction with the present regulations. Many stated that without the prohibition on redisclosure in § 2.32 of the current regulations the requirement for patient consent to a disclosure becomes meaningless. Some noted that the required notice to recipients of the prohibitions on redisclosure serves to inform the recipient of the confidential nature of the information when the recipient might not otherwise be sensitive to the need for confidentiality.

Negative responses totaled 45. Several of these were based on a belief that a prohibition on redisclosure is unenforceable. Other negative responses stated that a prohibition on redisclosure interferes with treatment, can cause unnecessary delays for patients, makes referrals cumbersome, and interferes with third party reimbursement.

Paragraph (d) § 2.12 of the proposed regulations retains the restrictions on redisclosure and use by the recipient of a disclosure made with written patient consent and §2.32 modifies the notice requirement for clarity and to reflect the prohibition in the authorizing statutes on use of alcohol and drug abuse patient records to criminally investigate or prosecute a patient.

The primary advantage of continuing the prohibition on redisclosure by recipients of a disclosure with patient consent is that it assures a greater measure of confidentiality for patient identifying information. It is particularly important to control redisclosures in view of proposed § 2.33 which drops the limitations in the current regulations on the categories of individuals and organizations to which disclosures may be made with patient consent and on the circumstances under which those disclosures may be made. Because it is frequently not easily ascertainable by a program whether a recipient of a redisclosure is in fact subject to these regulations, the proposal to require that the statement prohibiting redisclosure accompany all disclosures made with patient consent provides certainty for the programs and assures that all recipients of a disclosure with patient consent are put on notice concerning the prohibition on redisclosure.

With regard to the concern that the restriction on redisclosure is unenforceable, the Department notes that the confidentiality statutes restrict disclosure and use of the records themselves, rather than restricting disclosure and use by particular categories of persons holding the records (see §§ 2.12(d) and 2.12–1(g) of the current regulations) and that the regulations restrict redisclosure only if actual notice is given to the recipient of the record (see generally § 2.32–1(a) of the current regulations). In most cases, the actual notice of the prohibitions on redisclosure leads to voluntary compliance thus making it unnecessary to enforce the restriction through punitive measures. The proposed requirements for the content of the notice ensure uniformity and are not burdensome in that the statement is concise enough to be made a part of a disclosure form or to be stamped on the information to be released.

(i) Should the regulations be amended to permit disclosures with written consent to employers and employment agencies which are necessary to evaluate potential hazards created by a patient's employment even though that information may result in that patient being denied employment or advancement?

While § 2.38 of the current regulations permits disclosures concerning potential hazards to employers and employment agencies with patient consent, those disclosures are permitted only if a program has reason to believe that the information will be used to rehabilitate the patient and not to deny the patient employment or advancement. Many of the 231 affirmative responses urged that programs be relieved of the responsibility to making this determination about the use of the information. Some urged that disclosures be permitted to protect the safety and welfare of others, as well as the patient. Other responses stated that as a matter of right the patient should be able to take resonsibility for allowing a disclosure to the employer/employment agency without requiring the program to hold certain beliefs about how the recipient will use the information. Some responses urged that the patient be informed of the possible negative results of a disclosure to an employer/employment agency.

Negative responses total 122. Several of these comments feared that the proposed change would result in employment discrimination against the patient contrary to policies intended to prohibit discrimination against the handicapped. Some were concerned that the proposed change would result in a patient's being judged in terms of his or her treatment record rather than on the basis of his or her capacity to perform the job. Many responses urged that the program retain the right to exercise its own clinical judgement as to whether a particular disclosure should be made.

The proposed regulations simplify all of Subpart C—Disclosures with Patient's Consent, including the section dealing with employers and employment agencies, to permit disclosure to any individual or organization named in the consent (with some additional requirement for disclosures to central registries and in connection with

criminal justice referrals). The standard for permitting release of information with patient consent will be constant: a valid consent under § 2.31 and a determination that the information disclosed is necessary to carry out the purpose for which the consent was given (§ 2.31(a)). However, the regulations do not require that any disclosures be made by a program (see § 2.3(b)(1)).

An employer/employment agency may use the information which has been disclosed with patient consent to the detriment of the patient. However, this potential also exists under the present regulations because a program's belief about the intentions of an employer or employment agency may be inaccurate. Furthermore, if a program foresees such a detrimental use, there is nothing in the proposed regulations which would restrict a refusal to disclose.

(j) Should the regulations be amended to remove the prohibition on the entry of a court order authorizing the disclosure of communications by a patient to personnel of the program?

Affirmative responses totaled 72. The most frequent comment in favor of this change was that the responsibility of the court should encompass all types of patient information. Others said that the prohibition on courts authorizing the disclosure of "Communications" is unnecessary because the statutes require courts to find "good cause" for authorizing disclosure of patient information and that this good cause finding protects the patients against unreasonable disclosures. One response suggested that in addition to being unnecessary, the prohibition on disclosure of communications is unsupported by the statute. Some responses wondered how communications may be distinguished from any other information about the patient.

Negative responses totaled 214. More than half of these were submitted without comment. Many suggested that patients would be cautious about discussing information vital to therapy if a court could authorize a disclosure of a patient's communication to his or her counselor. Some suggested that communications are not reliable information anyway because they are subjective statements and are expressions of feelings or emotions of a temporary nature subject to misinterpretation. Some suggested that the amendment would not aid law enforcement but would cause programs to instruct patients not to discuss issues which could prove harmful to the patient, such as criminal activity.

The proposed regulations delete the provisions of § 2.63 which limit the scope of a court order to objective data. The Department sees no reasonable rationale for offering greater protection to communications and other subjective information obtained in the course of treatment. It is irrational and inequitable to restrict the courts in authorizing the disclosure of communications when there is no such restriction on disclosures to which a patient consents nor on those disclosures which are permitted without patient consent. Furthermore, the confidentiality statutes do not contemplate such a limitation in providing that disclosures may be made if "authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor."

From a practical point of view, the greatest advantage offered by elimination of the requirement that court orders may only authorize the disclosure of objective data is that it simplifies compliance with the regulations. There is no longer a need to make a distinction between the objective and subjective data in a patient's record. Another practical result is that the likelihood of a confrontation between programs and the courts on this issue is diminished.

A disadvantage in allowing a court to authorize disclosure of all information in a patient's record is that the disclosure of communications may be especially harmful to the patient if they involve admissions of criminal acts. However, Congress authorized the courts to balance the public interest in disclosure against the patient's interest in confidentiality in making its finding of good cause to issue an order removing the prohibition on disclosure. Any potential harm arising from the disclosure is best minimized through the statutory mandate that the courts impose appropriate safeguards against unauthorized disclosure, rather than through an inflexible, general prohibition which prevents courts from assessing good cause in certain instances.

(k) Should the procedures and criteria for entry of an authorizing court order be less detailed in order to simplify compliance by affected parties including the courts, law enforcement agencies, and programs?

Affirmative responses totaled 117. Several respondents suggested that simplification of the procedures would result in improved relationships among the affected parties. Other responses urged that the court order provisions be amended to allow hospitals and programs, upon service of a subpoena, to give the sealed records to the court for a determination of whether the disclosure should be authorized, thus relieving hospitals and programs of the burdens of appearing at a hearing and presenting evidence or arguments. A few responses suggested elimination of the requirement that a fictitious name be used to apply for a court order in favor of a requirement that the record of the proceedings be sealed from public scrutiny.

Negative responses totaled 139. Many negative respondents were satisfied that both client and program are protected by the detailed procedures and criteria. Others thought that a more general standard would cause confusion in interpretation and lead to a misuse of power. Some responses indicated that this portion of the regulations needs clarification, not substantive change.

The procedures and criteria for the entry of authorizing court orders have been rewritten for clarity and limited substantive changes have been made. A paragraph providing that the proceedings be conducted in the judge's chambers or in some other manner to avoid disclosure in the court order process has been added to each of the sections. Consistent with an interpretation of the current provisions, this paragraph states that the judge may examine the patient records referred to in the application for the order. In the section on orders authorizing disclosure and use of records to criminally investigate or prosecute patients, child abuse and neglect and the sale of illicit drugs have been added to the list of examples of crimes that cause or directly threaten loss of life or serious bodily injury. Again, this is consistent with interpretations of the current regulations.

Proposed procedures for the entry of orders authorizing a program to enroll or employ undercover agents and informants to criminally investigate employees or agents of a program will expedite the entry of those orders and eliminate burdensome requirements, but more restrictive criteria for the entry and content of such orders will insure that the action is based upon good cause.

(l) Should the regulations be amended to permit the disclosure of the patient status of an individual who commits or threatens to commit a crime on program premises or against program personnel?

The 222 affirmative responses reasoned that crimes must be reported and the offender prosecuted in order to protect program personnel and other patients and insure the efficient operation of the program. Some affirmative responses stipulated that the disclosure be limited in some way, e.g., to the circumstances of the criminal act.

The 69 negative responses were justified primarily on grounds that the program could make an adequate report to the police without disclosing patient status, and that relaxing the restriction would violate the patient's right to confidentiality and diminish basic trust in the program.

Section 2.12(c)(5) of the proposed regulations specifies that the restrictions on disclosure of information are not applicable to communications to law enforcement officers which: (1) Are directly related to the commission (or a threatened commission) of a crime on program premises or against program personnel, and (2) are limited to the circumstances surrounding the criminal threat or conduct. In addition, § 2.22 requires that the notification to patients of the confidentiality protections state that information related to a patient's commission (or a threatened commission) of a crime on the premises of the program or against personnel of the program is not protected under the regulations.

This change is intended to put patients on notice that there are limits to the behavior that will be tolerated in the treatment setting and to safeguard patients and program personnel against criminal acts. This approach may deter patients from engaging in criminal conduct because they will be put on notice that reports to law enforcement officers of actual or threatened crimes on program premises or against program personnel are not restricted in any way by these regulations.

The change makes it possible for program personnel to cooperate fully with law enforcement officials. Under the current regulations program personnel face the dilemma of being able to report crimes or threats of crime on program premises or against program personnel, but being unable to provide the officials useful information once they have responded to the request for assistance. This has led to failures to report, a disregard for the confidentiality restrictions and strained relations between programs and law enforcement personnel.

(m) Should the regulations be amended to permit the disclosure to law enforcement officials of the presence at a facility of a named individual without an authorizing court order?

Affirmative responses totaled 92. Many of these respondents considered any conflict between the requirements of State and Federal law (as implemented by these regulations) to be burdensome and wanted to eliminate this conflict by permitting acknowledgement of a patient's presence to law enforcement officials if permitted under State law. Some felt that an arrest or search warrant should be sufficient to authorize disclosure of the presence of a patient, while others felt that disclosure should be authorized in any situation involving suspected criminal behavior by a patient.

Negative responses totaled 194. Many felt that the patient's right to confidentiality would be violated if court order requirements were eliminated with regard to law enforcement inquiries concerning the presence of a named individual. Some simply expressed confidence that the courts are in the best position to balance the need for disclosure against the potential harm to the patient and the program-patient relationship. Others expressed concern that disclosure of a patient's presence to law enforcement officials would lead to harassment of patients, and eventually would undermine patient trust in the program. Several respondents suggested that law enforcement authorities have (and should use) means for locating persons other than by making inquiries to drug abuse treatment programs.

The proposed regulations continue the restriction in the current regulations upon the disclosure to anyone of information which would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person. However, § 2.13(c) has been added to clarify those conditions under which a program may acknowledge the presence of a patient. A more complete discussion of this issue appears under the heading "Implicit disclosures," which follows. In addition the proposed regulations add the Department's interpretation that the law and regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

The greatest advantage to leaving the regulations as they are with respect to this issue is that patient confidentiality is preserved and the routine use by law enforcement officials of programs to locate persons under investigation is precluded. Continuation of the current provision preserves the intent of the authorizing statutes to encourage alcohol and drug abusers to seek treatment and to rely on the courts to weigh relevant factors and determine whether "good cause" exists before making a disclosure of patient identifying information. In terms of a patient's incentive to seek or continue treatment an acknowledgement of presence to law enforcement officials can be as damaging as a disclosure of written records.

(n) Should the regulations be amended to remove the absolute prohibition on use of informants and undercover agents to investigate patients?

Affirmative responses totaled 35. These responses were justified on grounds that the prohibition confers rights on patients which are greater than those enjoyed by other citizens, and that the prohibition protects persons engaged in illegal conduct. A few affirmative responses were qualified, for example: That consent to investigate the patient by a law enforcement official first be obtained from the program director; that the prohibition be removed from alcohol programs only.

Negative responses totaled 227. These responses were justified most frequently on grounds that the programs are not intended to serve a law enforcement objective and that covert investigations are inherently destructive to a therapeutic relationship based on mutual trust. Many of the respondents argued that patient uncertainty about the use of informants and undercover agents to investigate them would have a negative impact on the effectiveness of not only programs where agents are placed but on all alcohol and drug abuse treatment programs.

The proposed regulations retain the absolute prohibition on the issuance of a court order to allow programs to enroll as a patient or employee undercover agents or informers to investigate patients.

This prohibition maintains the mutual trust essential to a therapeutic relationship by ensuring that patients are not made more vulnerable to investigation and prosecution because of their association with a treatment program than they would be if they had not sought treatment.

While the prohibition may interfere with some law enforcement investigations, it is believed that the effect will be minimal given the availability of other investigative avenues, and that this minimal interference is outweighed by the statutory purpose of encouraging alcohol and drug abusers to seek treatment by ensuring the privacy of the treatment relationship.

(o) Should the regulations continue to prohibit absolutely the disclosure and use of patient records for investigation or prosecution of nonserious crimes which are not committed on program premises or against personnel of the program?

Affirmative responses totaled 199. These responses supporting no change in the current regulations were justified on grounds that treatment objectives are

hampered by the intrusion of law enforcement personnel and that a patient's right to confidentiality outweighs societal benefits derived from use of patient records to investigate or prosecute crimes which are not serious.

Negative responses totaled 65. These responses were justified on grounds that a patient's medical status should not be a shield against pursuit of the societal interest in prosecuting any type of crime. Some of the negative responses were qualified, noting that there is no accepted criteria for distinguishing "serious" from "nonserious" crimes and that in certain situations (for example, suspected child abuse) programs should be free to cooperate with or even initiate an investigation.

Section 2.64 of the proposed regulations permits a court to authorize disclosure and use of patient records to investigate or prosecute any crime which "causes or directly threatens loss of life or serious bodily injury, such as homicide, rape, kidnaping, armed robbery, assault with a deadly weapon, child abuse and neglect, or the sale of illicit drugs." This proposal clarifies which crimes are covered, but the standard of confidentiality in the current regulations would be retained. This retention is based on the Department's determination that the public interest in the investigation and prosecution of crimes which do not cause or threaten loss of life or serious bodily injury or which are not committed, or threatened to be committed on program premises or against program personnel, does not outweigh the need to encourage treatment by ensuring confidentiality, given the availability of other avenues of investigation and other sources of evidence.

Other Substantive Amendments

Strict Construction of Regulations

Section 2.3(b)(3) of the proposed regulations states that the regulations are to be construed strictly in favor of the potential violator in the same manner as a criminal statute. The provision gives notice of the conclusion reached in a December 14, 1977 Opinion from the Office of Legal Counsel, United States Department of Justice, 1 Opinions Of The Office Of Legal Counsel 280 (GPO #270-000-00801-1, 1980), on the basis of the decision of the United States Supreme Court in *M. Krause & Bros.* v. *United States*, 327 U.S. 614, 621-622, 66 S.Ct. 705-08 (1946).

Definitions

The proposed regulations eliminate several of the current definitions because they are considered unnecessary and in some cases confusing, and clarify all the remaining definitions.

The definition of "funding source" has been shortened, clarified and incorporated into the definition of "third party payer." The definition of "service organization" has been incorporated into the definition of "qualified service organization."

The paragraph in the current regulations on "communications not constituting disclosure," which is not a definition, has been moved to the applicability section.

A definition of "disclose" or "disclosure" has been added to clarify what kinds of communications are restricted by the regulations.

As discussed above in connection with issue (c), the term "program" has been redefined to limit the extent to which the regulations apply to general medical care facilities. Applicability is limited to alcohol or drug abuse diagnosis, treatment or referral performed in units of the facility identified for that purpose or performed by staff identified as having the primary function of providing those services.

Applicability

In addition to limiting applicability to specialized alcohol and drug abuse programs (as defined in proposed § 2.11), and exempting from the regulatory restrictions limited communications from the program personnel to law enforcement officers regarding crimes on program premises or against program personnel (see § 2.12(c)(5)), the following provisions of proposed § 2.12, Applicability, are intended to reflect current provisions and interpretations of the statutes and regulations:

(1) The restrictions on use of patient information to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient in paragraphs (a)(2) and (d)(1) give notice of the prohibitions on use of patient information appearing in 42 U.S.C. 290ee-3(c) and 42 U.S.C. 290dd-3(c). In addition, the provisions of paragraph (d) make clear that the restriction on use applies to information obtained by undercover agents or informants and that it bars, among other things, the introduction of any patient information as evidence in a criminal proceeding. See *State* v. *Bethea*, 241 S.E. 2d 869 (N.C. Ct. App. 1978); *Armenta* v. *Superior Court of Santa Barbara County*, 61 Cal. App. 3d 584, 132 Cal. Rpt. 586 (1976).

(2) The exceptions to the applicability of the regulations in proposed paragraph (c), including: communications within a program needed to provide alcohol or drug abuse diagnosis, treatment or referral; communications between a program and a qualified service organization (appearing in § 2.11(p) of the current regulations); and the Veterans Administration and Armed Forces exceptions which appear in the current § 2.12(b).

(3) Paragraph (d) stating the applicability of the regulations to recipients of disclosures.

(4) The explanation of the scope of coverage of the regulations in paragraph (e). This explanation is based upon opinions of the Department's Office of the General Counsel interpreting the provisions of the current regulations. The opinions issued during the years 1975-1978 have been published in a booklet (DHHS Pub. No. (ADM) 81-1013, printed 1980) which may be purchased from the Superintendent of Documents, U.S. Government Printing Office, Washington, D.C. 20402. Copies of opinions issued in later years may be obtained from the National Institute on Drug Abuse or the National Institute on Alcohol Abuse and Alcoholism (see addresses in the proposed § 2.5).

Implicit disclosures

The prohibition in § 2.13(e) of the current regulations against implicit and negative disclosures has been very difficult to interpret and apply. Some of those subject to the regulations have mistakenly concluded that a hospital having both alcohol and drug abuse patient records and other types of medical records would have to handle all the records in compliance with the alcohol and drug abuse confidentiality regulations, since responding to requests for alcohol and drug abuse patient records in a different manner would implicitly disclose the alcohol or drug abuse problem of the patient. The proposed change in § 2.13(c)(2) attempts to resolve this situation by permitting, but not requiring, programs to inform inquiring parties of the restrictions of the confidentiality regulations if in doing so they do not affirmatively reveal that the regulations apply to the records of an identified patient. To some extent this permits an implicit disclosure that an individual is an alcohol or drug abuse patient. However, the Department believes that this resolution is a reasonable compromise given the limited harm which could be caused by such an implicit disclosure (it certainly could not be cited as reliable evidence since it would be based upon a supposition) and the basic unfairness and potential disruptive effect of failing to cooperate with an inquiring party. In

the absence of knowledge of the regulations the inquiring party could not seek a court order under Subpart E authorizing the program to make a disclosure and if the inquiring party is a law enforcement official a failure to cite the regulations might result in a disruptive search of the premises.

Disclosures of the Records of Deceased Patients for Cause of Death Inquiries

Section 2.16(b)(1) of the current regulations permitting disclosures of the records of deceased patients without consent has been expanded in proposed § 2.15(b) to include "the disclosure of patient identifying information relating to the cause of death of a patient under laws . . . permitting inquiry into the cause of death." This change responds to a number of complaints from coroners that the requirement for written consent by a personal representative or next of kin in the current regulations unreasonably interferes with their obligation under State and local laws to make inquiries into the cause of death of patients. In many cases no personal representative has been appointed and a family member cannot be located; thus, the cause of death inquiry cannot proceed unless the coroner is able to obtain a court order under Subpart E of the regulations authorizing the program to disclose the deceased patient's records. The Department believes these difficulties in pursuing an important obligation under State and local laws justify a change in the current regulations, particularly since there is a lesser necessity for protecting the confidentiality of alcohol or drug abuse records relating to a deceased patient.

Undercover Agents and Informants—Restriction applies only to programs

Section 2.19(b) (2) and (3) of the current regulations seeks to impose penalties upon law enforcement officials who take action directed toward the placement of undercover agents or informants in programs. These provisions have been removed from the proposed regulations because they represent an unnecessary expansion of the statutory restriction on the use of patient records to criminally investigative or prosecute patients. The clearly stated restriction in the proposed regulations on the use of any information obtained by an undercover agent or informant should be sufficient to deter law enforcement officials who seek to place undercover agents or informants in programs. Furthermore, this change is consistent with the strict construction standard applicable to a statute imposing a criminal penalty (see proposed § 2.3(b)(3)).

Disclosures With Written Consent, Subpart C

This subpart has been revised substantially to: (1) Eliminate most of the sections setting forth special rules for disclosure with written consent in certain circumstances and (2) set forth a sample consent form containing each of the elements required under § 2.31. With the exception of the sections pertaining to disclosure with written consent to central registries and in connection with criminal justice referrals, the Department believes that the current provisions of Subpart C impose compliance burdens which are disproportionate to the confidentiality protection afforded. Sufficient protection is provided through the specificity of the consent form (see § 2.31) and the requirement that all disclosures under the regulations be limited to that information which is necessary to carry out the purpose of the disclosure (see § 2.13(a)). This approach is consistent with the recommendations of the Privacy Protection Study Commission regarding the confidentiality of records in medical care relationships. (See recommendation 11 and recommendation 13 of the Report of the Commission at 313, 315.)

Special rules for disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs (proposed § 2.34) and for disclosures to elements of the criminal justice system which have referred patients (proposed § 2.35) have been retained because these types of disclosure necessitate some adjustment of the basic written consent procedures in order to insure maximum protection for patients. Under § 2.34 the timing, content and use of the patient information is strictly limited in accordance with the purpose of the disclosure. Under § 2.35 a disclosure in connection with a criminal justice referral can be made only to those having a need for the information in connection with their duty to monitor the patient's progress. On the other hand, the rules in § 2.35 regarding duration of consent and revocation of consent are more lenient than those which generally apply in order to facilitate the exchange of information and the monitoring of a patient's progress. These changes will encourage referrals for treatment from the criminal justice system by simplifying the confidentiality restrictions without lessening the protections afforded.

Disclosures Without Consent, Subpart D

Section 2.51 Medical emergencies. Paragraph (a) would be amended to provide specifically that a bona fide medical emergency exists if any individual is suffering from a condition which poses an immediate threat to his or her health and which requires immediate medical intervention.

Paragraph (c) "Incapacitated persons," would be deleted because it does not add anything to the basic provision permitting disclosures to medical personnel to the extent necessary to meet a bona fide medical emergency. While the incapacity of the patient may be a factor in determining whether such an emergency exists, incapacity does not per se constitute an emergency.

Paragraph (d) "Notification of family or others," would be deleted based upon the Department's conclusion that by permitting notification of family or others without patient consent, it exceeds the statutory authority for disclosures to "medical personnel to the extent necessary to meet a bona fide medical emergency."

Because the statute permits a disclosure only to medical personnel, a requirement that the program make a reasonable effort to verify the medical personnel status of any proposed recipient would be added and the current requirement for documentation of oral disclosures would be expanded to include the health care facility affiliation of the medical personnel and the details of the attempt to verify their status.

The special rule permitting disclosures to medical personnel of the Food and Drug Administration for the purpose of notifying patients or their physicians of potential dangers arising from the manufacture, labeling or sale of a product under FDA jurisdiction has been retained becaue this situation constitutes a bona fide medical emergency which might not be recognized as such in the absence of explicit notice in these regulations.

Section 2.52 Research Activities. This section of the proposed regulations combines, shortens, and to some extent changes the provisions governing disclosures for research purposes in § 2.52 and § 2.53 of the current regulations.

The current § 2.52 attempts to define "qualified personnel," but ultimately leaves it to the program to determine whether those personnel have "training and experience . . . appropriate to the nature and level of work in which they are engaged." In addition the current § 2.53(a) creates some confusion by stating that where research is performed by a State or Federal governmental agency the minimum qualifications of

personnel performing that function may be determined by the agency. To resolve these problems the determination of whether an individual is qualified to conduct the research would be left to the program director. The Department believes that program directors are qualified to make this determination and that the requirement for such a determination reflects reality in that qualifications for conducting research cannot be defined with sufficient specificity to avoid the exercise of some discretion on the part of the program.

Paragraph (b)(3), of the current § 2.52 providing for a redisclosure to avoid a substantial risk to the health and well-being of any patient, would be deleted. The basis for this provision is uncertain in light of the clear statutory prohibition on any redisclosure of patient identifying information. Furthermore, if some contacting of patients is necessary in order to avoid such a substantial threat, it appears that this could be carried out through the program, or would be permissible because it would not involve the communication of patient identifying information (see the definition of "disclosure" in proposed § 2.11).

§ 2.53 Audit and evaluation activities. This proposed section is patterned primarily after the current § 2.54. The current § 2.53 and § 2.55 would be eliminated. The Department believes that these sections are unnecessary and confusing because they repeat matters which are addressed in other statutes and regulations, impose restrictions upon those conducting the audit or evaluation activities beyond what is necessary to insure protection of the alcohol or drug abuse patient records and provide special treatment for one class of audit and evaluation activities with no compelling justification.

Proposed § 2.53 is intended to provide protections for alcohol and drug abuse patient records which can be readily complied with in all audit and evaluation situations. While the proposed section simplifies the current regulatory provisions, it provides greater protection for alcohol and drug abuse patient records. Under the current § 2.54 any individual may copy or remove patient records in the course of audit or evaluation activities if he complies with the regulatory requirements. Under the proposed § 2.53, records containing patient identifying information may be copied or removed from program premises only by those individuals "paid to perform the audit or evaluation activity by a Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities." If copying or removal of patient identifying information is not involved, the proposed § 2.53 permits a disclosure of patient identifying information to any person who is determined by the program director to be qualified to conduct the audit or evaluation activities as well as to auditors paid by governmental agencies which assist or regulate the program. Whether or not records are copied or removed, the auditor or evaluator must agree in writing to comply with the limitations on disclosure and use in paragraph (c) of the proposed § 2.53. If patient identifying information is copied or removed, the auditor or evaluator must also agree in writing to maintain the patient identifying information in accordance with the security requirements under the proposed § 2.16 and to destroy all patient identifying information upon completion of the audit or evaluation.

This proposal simplifies and lessens the burden of the retention period provisions in the current § 2.54, but does not lessen the confidentiality protections since the security requirements and the restrictions on disclosure and use apply while the copies of the records are held by the auditor or evaluator.

Substantive Amendments Suggested in Comments but Not Proposed

The public comments suggested several substantive amendments beyond those addressed in the Notice of Decision to Develop Regulations. These suggested amendments are not proposed for the following reasons.

Changes not permitted by the authorizing statutes

Several comments suggested amendments which would not be authorized under the statutes protecting the confidentiality of alcohol abuse patient records (42 U.S.C. 299dd–3) and drug abuse patient records (42 U.S.C. 290ee–3). Examples of these suggested amendments include: (1) A request that the regulations allow disclosures without consent among various institutions involved in the referral of patients (the statutes permit disclosures without written consent only to meet bona fide medical emergencies, for the purpose of conducting scientific research, management audits, financial audits or program evaluation, or if authorized by an appropriate order of a court of competent jurisdiction); (2) suggestions that the regulations impose a penalty upon anyone seeking to obtain patient records by fraudulent means (all the restrictions in the statutes apply to persons responsible for maintaining the records, not those seeking them and, as noted above, the statutes must be strictly construed); (3) a suggestion that the regulations be applied to other medical records (the authorizing statutes are clearly limited to alcohol and drug abuse patient records).

Amendments based upon misinterpretation of the current regulations

It was requested that the provisions governing qualified service organization agreements, § 2.11 (m), (n) and (p)(2) of the current regulations, be amended to permit the disclosure of information identifying the patient. Patient identifying information can, under the current regulations, be disclosed under a qualified service organization agreement. It was also urged that general hospitals be permitted to reveal that an individual is a patient in the hospital unless doing so would identify the individual as an alcohol or drug abuser. Section § 2.13(f) of the current regulations permits such a disclosure. Another comment suggested that the provisions of the current regulations governing disclosures without consent for the purpose of conducting research, audit or evaluation be amended to permit the research, audit and evaluation reports to be released in summary form without patient identifying information. The current § 2.52 permits such a disclosure.

Disclosures to protect health or safety

Several comments sought amendments which would permit disclosures without consent in situations where the patient's condition might endanger the health or safety of others, e.g., an intoxicated bus driver. The Department also notes that the recommendations of the Privacy Protection Study Commission regarding confidentiality of all medical records would permit disclosures without consent "to a properly identified recipient pursuant to a showing of compelling circumstances affecting the health and safety of an individual." (Report at 306).

However, the statutes authorizing these regulations strictly limit disclosures without consent and would permit such a disclosure in a situation where health or safety is threatened only if: (1) Authorized by an appropriate order of a court of competent jurisdiction based upon a finding of good cause; or (2) the disclosure is made to medical personnel to the extent necessary to meet a bona fide medical emergency. Thus, the Department may

not permit by regulation disclosures of patient records beyond these limited disclosures permitted by the statutes. Nevertheless, by defining disclosures to include only communications which would identify a patient as an alcohol or drug abuser, the regulations permit providers of alcohol or drug abuse treatment to warn of potential threats to health or safety if this is done in a way that does not identify an individual as an alcohol or drug abuse patient.

Child Abuse and Neglect Reporting

A number of comments requested changes in the regulations to permit alcohol and drug abuse treatment personnel to comply with State child abuse and neglect reporting laws. Many of these comments misconstrue the extent to which the current regulations restrict this reporting and do not take cognizance of the Department's interpretation of the current regulations to allow child abuse and neglect reporting to the greatest extent possible.

The authorizing statutes do not categorically except disclosures in connection with the reporting of child abuse and neglect from the restrictions on the disclosure and use of alcohol and drug abuse patient records. Thus, the Department cannot by regulation abrogate the statutory restrictions where a disclosure is made in connection with the reporting of child abuse or neglect. However, it is the policy of the Department to encourage providers of alcohol and drug abuse services to report instances of child abuse and neglect where this can be done in conformity with the statutory confidentiality protections.

Accordingly, under the proposed regulations, child abuse and neglect may be reported as follows:

(1) A report may be made pursuant to a court order authorizing disclosure for noncriminal purposes (see proposed § 2.63) or authorizing disclosure and use for the criminal investigation or prosecution of patients (see proposed § 2.64). The proposed regulations at § 2.64(d)(1) list specifically child abuse and neglect as a crime for which a court order may be issued under § 2.64. (See the preamble discussion of issue (o)).

The proposed regulations further expand the potential for reporting child abuse and neglect prusuant to a court order by removing the limitation which now exists in § 2.63 on the scope of a court order. Under the existing regulations, a court order is restricted to objective data and may not extend to communications by a patient to personnel of a program, such as a statement by the patient that the patient is abusing or neglecting a child. The proposed regulations delete the provisions of § 2.63 which limit the scope of a court order to objective data. (See the preceding discussion of issue (j)).

(2) A report may be made if it does not identify a patient as an alcohol or drug abuser. Neither the current regulations (see § 2.11(p)(3)) nor the proposed regulations (see proposed § 2.12(a)(1)(i)) restrict communications which do not identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information or through verification of such an identification made by another person.

(3) A report may be made if the patient consents in writing in accordance with § 2.31. The proposed regulations eliminate those sections governing disclosures with written consent in specific circumstances, other than disclosures to central registries and in connection with criminal justice referrals, in favor of a section which permits any disclosure to which the patient has consented by signing the required written statement (see proposed § 2.33, the preamble discussion titled "Disclosures With Written Consent, Subpart C" and the preceding discussions of issues (f), (g), and (i)). As a consequence, the proposal eliminates the requirement that a program must determine that "disclosure will not be harmful to the patient" before disclosing information with the patient's consent under § 2.40 of the current regulations. Thus, if a patient consents to the reporting of child abuse or neglect under §§ 2.31 and 2.33, the proposed regulations would permit that reporting without a finding that the disclosed may not be used for purposes of a criminal investigation or prosecution of the patient unless an authorizing court order is obtained under proposed § 2.64 because under subsection (c) of the authorizing statutes and §§ 2.12 (a)(2) and (d)(1) of the proposed regulations a court order is required in order to use a patient record for those purposes.

(4) A report may be made pursuant to a qualified service organization agreement (see § 2.11(n)) of the current regulations and § 2.11 of the proposed regulations). The Department encourages under the current regulations and would continue to encourage under the proposed regulations, providers of alcohol and drug abuse services which are subject to the regulations to enter into "qualified service organization agreements" with child protective agencies, so the providers may comly with both the confidentiality regulations and the child abuse reporting laws. (For a discussion of this issue under the current regulations, see Alcohol Health and Research World, Fall 1979, p. 31 *et. seq.*). Such an agreement permits the provider of alcohol and drug abuse services to disclose patient information to the child abuse protective agency, even though the patient has not consented (see § 2.11(p)(2) of the current regulations and § 2.12(c)(4) of the proposed regulations).

Under a "qualified service organization agreement" the child abuse protective agency must handle the information obtained from the alcohol or drug abuse provider in compliance with the confidentiality regulations. Thus, the agency may disclose information which would identify the patient as an alcohol or drug abuser only with the patient's consent in accordance with Subpart C of the regulations, without patient consent in the limited circumstances described in Subpart D, or under an authorizing court order entered in accordance with Subpart E.

If a child abuse protective agency wants to use the information obtained under the qualified service organization agreement for the purpose of investigating or prosecuting any criminal child abuse or neglect charges against the alcohol or drug abuse patient it must obtain an authorizing court order under § 2.65 of the current regulations or § 2.64 of the proposed regulations. In order to clarify that child abuse or neglect may be found to be a crime directly threatening loss of life or serious bodily injury for which an authorizing order may be issued, child abuse and neglect is listed as an example of such a crime under § 2.64(d)(1) of the proposed regulations.

To clarify and facilitate use of the Department's policy recommending that providers of alcohol and drug abuse services enter into qualified service organization agreements with child protection agencies, the proposed § 2.11 defines a "qualified service organization" so that it includes provision of services "to prevent or treat child abuse or neglect, including training on nutrition and child care, and individual and group therapy."

(5) A report may be made to medical personnel if it is done for the purpose of treating the child for a medical emergency (see proposed § 2.51). The proposed regulations limit a medical emergency to those conditions which pose an immediate threat to health and which require immediate medical intervention. They also clarify that a medical emergency may be that of any individual, not solely that of the patient.

Proposed § 2.13 limits any disclosure to that information which is necessary to carry out the purpose of the disclosure—in this case to treat a condition which immediately threatens the health of a child. Thus, proposed § 2.51 would permit alcohol and drug abuse treatment personnel to report to medical personnel patient identifying information if the medical personnel have a need for the information to treat an abused or neglected child in a bona fide medical emergency; that is, to treat a child with a condition which immediately threatens the child's health and which requires immediate medical intervention. If the threat to the child's health is not immediate and does not require immediate medical intervention, other permitted disclosures may serve to protect the child's health, such as a court ordered disclosure, a report which does not disclose that a patient is an alcohol or drug abuser, or a disclosure with patient consent.

Economic Impact of Regulatory Requirements

Not a Major Rule Under E.O. 12291

The Department has determined that this rule is not a "major rule" under Executive Order 12291. Overall costs to general medical care facilities will be reduced as a result of the decision to apply the regulations only to specialized alcohol and drug abuse treatment programs. Furthermore, cost to specialized programs will be reduced somewhat by the simplified rules, although not significantly since the proposal would continue to require strict confidentiality standards.

Thus a regulatory analysis is not required because the proposed regulation will not:

(1) Have an annual effect on the economy of $100 million or more;

(2) Impose a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies or geographic regions; or

(3) Result in significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

No Significant Impact on a Substantial Number of Small Entities

Subsequent to the January 1980 Notice of Decision to Develop Regulations the Department indicated in its Semi-Annual Agenda of Regulations that under the Regulatory Flexibility Act, Pub. L. 96-354, a regulatory flexibility analysis would be prepared in connection with this proposed amendment of the confidentiality regulations. That determination was based on the probability that the regulations would continue to apply to all entities performing alcohol or drug abuse prevention functions which are federally assisted, regulated, or conducted. However, this Notice of Proposed Rulemaking reflects a decision to limit applicability to providers of alcohol or drug abuse diagnosis, treatment or referral who hold themselves out as such. Based on that decision, it has been determined that the proposed regulations will not have a significant economic impact on a substantial number of small entities. By reason of the proposed change in applicability: (1) The regulations will no longer apply to general medical care providers which render alcohol or drug abuse services incident to their general medical care functions, thus the number of small entities affected will be less than substantial; and (2) the economic impact will be less than significant because that impact arises primarily from the costs of determining that the records of a general medical care patient are subject to the regulations and thereafter treating those records differently than all other general medical care records. It is anticipated that providers to whom these rules are applicable will realize a small savings through an overall reduction in the complexity of the rules.

Information Collection Requirements

Sections 2.22, 2.31(a) and 2.51(c)(2) of this proposed rule contain information collection requirements. As required by section 3504(h) of the Paperwork Reduction Act of 1980, we have submitted a copy of this proposed rule to the Office of Management and Budget (OMB) for its review of these information collection requirements. Other organizations and individuals desiring to submit comments on the information collection requirements should direct them to the agency official designated for this purpose whose name appears in this preamble, and to the Office of Information and Regulatory Affairs, OMB, New Executive Office Building (Room 3208), Washington, D.C. 20503, ATTN: Desk Officer for HHS.

List of Subjects in 42 CFR Part 2

Alcohol abuse, Alcoholism, Confidentiality, Drug abuse, Health records, Privacy.

Dated: November 5, 1982.

Edward N. Brandt, Jr.,

Assistant Secretary for Health.

Approved: July 6, 1983.

Margaret M. Heckler,

Secretary.

It is proposed to revise 42 CFR Part 2 as follows:

PART 2—CONFIDENTIALITY OF ALCOHOL AND DRUG ABUSE PATIENT RECORDS

Subpart A—Introduction

Sec.

Subpart B—General Provisions

Authority: Sec. 408 of Pub. L. 92–255, 86 Stat. 79, as amended by sec. 303(a), (b) of Pub. L. 93–282, 88 Stat. 137, 138; sec. 4(c)(5)(A) of Pub. L. 94–237, 90 Stat. 244; sec. 111(c)(3) of Pub. L. 94–581, 90 Stat. 2852; sec. 509 of Pub. L. 96–88, 93 Stat. 695; sec. 973(d) of Pub. L. 97–35, 95 Stat. 598; and transferred to sec. 527 of the Public Health Service Act by sec. 2(b)(16)(B) of Pub. L. 98–24, 97 Stat. 182 (42 U.S.C. 290ee–3) and sec. 333 of Pub. L. 91–616, 84 Stat. 1853, as amended by sec. 122(a) of Pub. L. 93–282, 88 Stat. 131; and sec. 111(c)(4) of Pub. L. 94–581, 90 Stat. 2852 and transferred to sec. 523 of the Public Health Service Act by sec. 2(b)(13) of Pub. L. 98–24, 97 Stat. 181 (42 U.S.C. 290dd–3).

Subpart A—Introduction

§ 2.1 Statutory authority for confidentiality of drug abuse patient records.

The restrictions of these regulations upon the disclosure and use of drug abuse patient records were authorized by section 408 of the Drug Abuse Prevention, Treatment, and Rehabilitation Act (21 U.S.C. 1175). That section was recently transferred by Pub. L. 98–24 to section 527 of the Public Health Service Act. As a result of the transfer, in the future the provision will be codified at 42 U.S.C. 290ee–3. For the present it remains at 21 U.S.C. 1175 which is set forth below:

§ 1175. Confidentiality of patient records

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bonafide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations; interagency consultations; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary of Health, Education, and Welfare, after consultation with the Administrator of Veterans' Affairs and the heads of other Federal departments and agencies substantially affected thereby, shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

[Subsection (h) was superseded by section 111(c)(3) of Pub. L. 94–581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of drug abuse patient records under Title 38 was moved from 21 U.S.C. 1175 to 38 U.S.C. 4134.)

§ 2.2 Statutory authority for confidentiality of alcohol abuse patient records.

The restrictions of these regulations upon the disclosure and use of alcohol abuse patient records were authorized by 333 of the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970 (42 U.S.C. 4582). That section was recently transferred by Pub. L. 98–24 to section 523 of the Public Health Service Act. As a result of the transfer, in the future the provision will be codified at 42 U.S.C. 290dd–3. For the present it remains at 42 U.S.C. 4582 which is set forth below:

§ 4582. Confidentiality of patient records

(a) Disclosure authorization

Records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any program or activity relating to alcoholism or alcohol abuse education, training, treatment, rehabilitation, or research, which is conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section.

(b) Purposes and circumstances of disclosure affecting consenting patient and patient regardless of consent

(1) The content of any record referred to in subsection (a) of this section may be disclosed in accordance with the prior written consent of the patient with respect to whom such record is maintained, but only to such extent, under such circumstances, and for such purposes as may be allowed under regulations prescribed pursuant to subsection (g) of this section.

(2) Whether or not the patient, with respect to whom any given record referred to in subsection (a) of this section is maintained, gives his written consent, the content of such record may be disclosed as follows:

(A) To medical personnel to the extent necessary to meet a bona fide medical emergency.

(B) To qualified personnel for the purpose of conducting scientific research, management audits, financial audits, or program evaluation, but such personnel may not identify, directly or indirectly, any individual patient in any report of such research, audit, or evaluation, or otherwise disclose patient identities in any manner.

(C) If authorized by an appropriate order of a court of competent jurisdiction granted after application showing good cause therefor. In assessing good cause the court shall weigh the public interest and the need for disclosure against the injury to the patient, to the physician-patient relationship, and to the treatment services. Upon the granting of such order, the court, in determining the extent to which any disclosure of all or any part of any record is necessary, shall impose appropriate safeguards against unauthorized disclosure.

(c) Prohibition against use of record in making criminal charges or investigation of patient

Except as authorized by a court order granted under subsection (b)(2)(C) of this section, no record referred to in subsection (a) of this section may be used to initiate or substantiate any criminal charges against a patient or to conduct any investigation of a patient.

(d) Continuing prohibition against disclosure irrespective of status as patient

The prohibitions of this section continue to apply to records concerning any individual who has been a patient, irrespective of whether or when he ceases to be a patient.

(e) Armed Forces and Veterans' Administration; interchange of records

The prohibitions of this section do not apply to any interchange of records—

(1) within the Armed Forces or within those components of the Veterans' Administration furnishing health care to veterans, or

(2) between such components and the Armed Forces.

(f) Penalty for first and subsequent offenses

Any person who violates any provision of this section or any regulation issued pursuant to this section shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

(g) Regulations of Secretary; definitions, safeguards, and procedures, including procedures and criteria for issuance and scope of orders

Except as provided in subsection (h) of this section, the Secretary shall prescribe regulations to carry out the purposes of this section. These regulations may contain such definitions, and may provide for such safeguards and procedures, including procedures and criteria for the issuance and scope of orders under subsection (b)(2)(C) of this section, as in the judgment of the Secretary are necessary or proper to effectuate the purposes of this section, to prevent circumvention or evasion thereof, or to facilitate compliance therewith.

(Subsection (h) was superseded by section 111(c)(4) of Pub. L. 94-581. The responsibility of the Administrator of Veterans' Affairs to write regulations to provide for confidentiality of alcohol abuse patient records under Title 38 was moved from 42 U.S.C. 4582 to 38 U.S.C. 4134.)

§ 2.3 Purpose and effect.

(a) *Purpose.* Under the statutory provisions quoted in §§ 2.1 and 2.2, these regulations impose restrictions upon the disclosure and use of alcohol and drug abuse patient records which are maintained in connection with the performance of any federally assisted alcohol or drug abuse program. The regulations specify:

(1) Definitions, applicability, and general restrictions in Subpart B;

(2) Disclosures which may be made with written patient consent and the form of the written consent in Subpart C;

(3) Disclosures which may be made without written patient consent or an authorizing court order in Subpart D; and

(4) Disclosures and uses of patient records which may be made with an authorizing court order and the procedures and criteria for the entry and scope of those orders in Subpart E.

(b) *Effect.* (1) These regulations prohibit the disclosure and use of patient records unless certain circumstance exist. If any circumstances exists under which disclosure is permitted, that circumstance acts to remove the prohibition on disclosure but it does not compel disclosure. Thus, the regulations do not require disclosure under any circumstance.

(2) These regulations are not intended to direct the manner in which substantive functions such as research, treatment, and evaluation are carried out. They are intended to insure that an alcohol or drug abuse patient in a federally assisted alcohol or drug abuse program is not made more vulnerable by reason of the availability of his or her patient record than an individual who has an alcohol or drug problem and who does not seek treatment.

(3) Because there is a criminal penalty a fine—see (42 U.S.C. 290ee-3(f), 42 U.S.C. 290dd-3(f) and 42 CFR § 2.4) for violating the regulations, they are to be construed strictly in favor of the potential violator in the same manner as a criminal statute (see *M. Kraus & Brothers* v. *United States*, 327 U.S. 614, 621-22, 66 S. Ct. 705, 707-08 (1946)).

§ 2.4 Criminal penalty for violation.

Under 42 U.S.C. 290ee-3(f) and 42 U.S.C. 290dd-3(f), any person who violates any provision of those statutes or these regulations shall be fined not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

§ 2.5 Reports of violations.

(a) The report of any violation of these regulations may be directed to the United States Attorney for the judicial district in which the violation occurs.

(b) The report of any violation of these regulations involving a drug abuse patient record may be directed to:

Director, National Institute on Drug Abuse, 5600 Fishers Lane, Rockville, Maryland 20857

(c) The report of any violation of these regulations involving an alcohol abuse patient record may be directed to:

Director, National Institute on Alcohol Abuse and Alcoholism, 5600 Fishers Lane, Rockville, Maryland 20857

(d) The report of any violation of these regulations by a methadone program may be directed to the Regional Offices of the Food and Drug Administration.

(e) The report of any violation of these regulations by a Federal agency or a Federal grantee or contractor may be directed to the Federal agency responsible for the program or for monitoring the grant or contract.

Subpart B—General Provisions

§ 2.11 Definitions.

For purposes of these regulations:

Alcohol abuse means the use of an alcoholic beverage which impairs the physical, mental, emotional, or social well-being of the user.

Drug abuse means the use of a psychoactive substance for other than medicinal purposes which impairs the

physical, mental, emotional, or social well-being of the user.

Central registry means an organization which obtains from two or more member programs patient identifying information about individuals applying for maintenance treatment or detoxification treatment for the purpose of avoiding an individual's concurrent enrollment in more than one program.

Detoxification treatment means the dispensing of a narcotic drug in decreasing doses to an individual in order to reduce or eliminate adverse physiological or psychological effects incident to withdrawal from the sustained use of a narcotic drug.

Diagnosis means any reference to an individual's alcohol or drug abuse or to a condition which is identified as having been caused by that abuse which is made for the purpose of treatment or referral for treatment.

Disclose or *disclosure* means a communication of patient indentifying information, the affirmative verification of another person's communication of patient identifying information, or the communication of any information from the record of a patient who has been identified.

Informant means an individual:

(a) Who is a patient or employee of a program or who becomes a patient or employee of a program at the request of a law enforcement agency or official; and

(b) Who at the request of a law enforcement agency or official observes one or more patients or employees of the program for the purpose of reporting the information obtained to the law enforcement agency or official.

Maintenance treatment means the dispinsing of a narcotic drug in the treatment of an individual for dependence upon heroin or other morphine-like drugs.

Member program means a detoxification treatment or maintenance treatment program which reports patient identifying information to a central registry and which is in the same State as that central registry or is not more than 125 miles from any border of the State in which the central registry is located.

Patient means any individual who has applied for or been given diagnosis or treatment for alcohol or drug abuse at a federally assisted program and includes any individual who, after arrest on a criminal charge, is identified as an alcohol or drug abuser in order to determine that individual's eligibility to participate in a program.

Patient identifying information means the name, address, social security number, fingerprints, photograph, or similar information by which the identity of a patient can be determined with reasonable accuracy and speed either directly or by reference to other publicly available information. The term does not include a number assigned to a patient by a program, if that number does not consist of, or contain numbers (such as a social security, or driver's license number) which could be used to identify a patient with reasonable accuracy and speed.

Person means an individual, partnership, corporation, Federal, State or local governmental agency, or any other legal entity.

Program means a person which in whole or in part holds itself out as providing, and provides, alcohol or drug abuse diagnosis, treatment, or referral for treatment. For a general medical care facility or any part thereof to be a program, it must have:

(a) An identified unit which provides alcohol or drug abuse diagnosis, treatment, or referral for treatment or

(b) Medical personnel or other staff whose primary function is the provision of alcohol or drug abuse diagnosis, treatment, or referral for treatment and who are identified as such providers.

Program director means:

(a) In the case of a program which is an individual, that individual;

(b) In the case of a program which is an organization, the individual designated as director, managing director, or otherwise vested with authority to act as chief executive of the organization.

Qualified service organization means a person which:

(a) Provides services to a program, such as data processing, bill collecting, dosage preparation, laboratory analyses, or legal, medical, accounting, or other professional services, or services to prevent or treat child abuse or neglect, including training on nutrition and child care and individual and group therapy; and

(b) Has entered into a written agreement with a program under which that person:

(1) Acknowledges that in receiving, storing, processing or otherwise dealing with any patient records from the programs, it is fully bound by these regulations; and

(2) If necessary, will resist in judicial proceedings any efforts to obtain access to patient records except as permitted by these regulations.

Records means any information, whether recorded or not, relating to a patient, received or acquired by a federally assisted alcohol or drug program.

Third party payer means a person who pays, or agrees to pay, for diagnosis or treatment furnished to a patient on the basis of a contractual relationship with the patient or a member of his family or on the basis of the patient's eligibility for Federal, State, or local governmental benefits.

Treatment means the management and care of a patient suffering from alcohol or drug abuse, a condition which is identified as having been caused by that abuse, or both, in order to reduce or eliminate the adverse effects upon the patient.

Undercover agent means an officer of any Federal, State, or local law enforcement agency who enrolls in or becomes an employee of a program for the purpose of investigating a suspected violation of law or who pursues that purpose after enrolling or becoming employed for other purposes.

§ 2.12 Applicability

(a) *General*—(1) *Restrictions on disclosure.* The restrictions on disclosure in these regulations apply to any information, whether or not recorded, which:

(i) Would identify a patient as an alcohol or drug abuser either directly, by reference to other publicly available information, or through verification of such an identification by another person; and

(ii) Is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date) for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(2) *Restriction on use.* The restriction on use of information to initiate or substantiate any criminal charges

against a patient or to conduct any criminal investigation of a patient (42 U.S.C. 290ee–3(c), 42 U.S.C. 290dd–3(c)) applies to any information, whether or not recorded which is drug abuse information obtained by a federally assisted drug abuse program after March 20, 1972, or is alcohol abuse information obtained by a federally assisted alcohol abuse program after May 13, 1974 (or if obtained before the pertinent date, is maintained by a federally assisted alcohol or drug abuse program after that date as part of an ongoing treatment episode which extends past that date), for the purpose of treating alcohol or drug abuse, making a diagnosis for that treatment, or making a referral for that treatment.

(b) *Federal assistance.* An alcohol abuse or drug abuse program is considered to be federally assisted if:

(1) It is conducted in whole or in part, whether directly or by contract or otherwise, by any department or agency of the United States (but see paragraphs (c)(1) and (c)(2) of this section relating to the Veterans' Administration and the Armed Forces);

(2) It is being carried out under a license, certification, registration, or other authorization granted by any department or agency of the United States including:

(i) Certification of provider status under the Medicare program;

(ii) Authorization to conduct methadone maintenance treatment (see 21 CFR 291.505); or

(iii) Registration to dispense a substance under the Controlled Substances Act to the extent the controlled substance is used in the treatment of alcohol or drug abuse;

(3) It is supported by funds provided by any department or agency of the United States by being:

(i) A recipient of Federal financial assistance in any form, including financial assistance which does not directly pay for the alcohol or drug abuse diagnosis, treatment, or referral activities; or

(ii) Conducted by a State or local government unit which, through general or special revenue sharing or other forms of assistance, receives Federal funds which could be (but are not necessarily) spent for the alcohol or drug abuse program; or

(4) It is assisted by the Internal Revenue Service of the Department of the Treasury through the allowance of income tax deductions for contributions to the program or through the granting of tax exempt status to the program.

(c) *Exceptions*—(1) *Veterans' Administration.* These regulations do not apply to information on alcohol and drug abuse patients maintained in connection with the Veterans' Administraton provision of hospital care, nursing home care, domiciliary care, and medical services under Title 38, United States Code. Those records are governed by 38 U.S.C. 4132 and regulations issued under that authority by the Administrator of Veterans' Affairs.

(2) *Armed Forces.* These regulations apply to any information described in paragraph (a) of this section which was obtained by any component of the Armed Forces during a period when the patient was subject to the Uniform Code of Military Justice except:

(i) Any interchange of that information within the Armed Forces; and

(ii) Any interchange of that information between the Armed Forces and those components of the Veterans Administration furnishing health care to veterans.

(3) *Communications within a program.* The restrictions on disclosure in these regulations do not apply to communications of information within a program between or among personnel having a need for the information in connection with a patient's diagnosis, treatment, or referral for treatment of alcohol or drug abuse.

(4) *Qualified Service Organizations.* The restrictions on disclosure in these regulations do not apply to communications between a program and a qualified service organization of information needed by the organization to provide services to the program.

(5) *Crimes on program premises or against program personnel.* The restrictions on disclosure and use in these regulations do not apply to communications from program personnel to law enforcement officers which–

(i) Are directly related to a patient's commission of a crime on the premises of the program or against program personnel or to a threat to commit such a crime; and

(ii) Are limited to the circumstances of the incident, including the patient status of the individual committing or threatening to commit the crime, that individual's name and address, and that individual's last know whereabout.

(d) *Applicability to recipients of information*—(1) *Restriction on use of information.* The restriction on the use of any information subject to these regulations to initiate or substantiate any criminal charges against a patient or to conduct any criminal investigation of a patient applies to any person who obtains that information from a federally assisted alcohol or drug abuse program, regardless of the status of the person obtaining the information or of whether the information was obtained in accordance with these regulations. This restriction on use bars, among other things, the introduction of that information as evidence in a criminal proceeding and any other use of the information to investigate or prosecute a patient with respect to a suspected crime. Information obtained by undercover agents or informants (see § 2.17) or through patient access (see § 2.23) is subject to the restriction on use.

(2) *Restrictions on disclosures—Third party payers and others.* The restrictions on disclosure in these regulations apply to third party payers who maintain patient records disclosed to them by federally assisted alcohol or durg abuse programs and to those persons—

(i) Who receive patient records directly from a federally assisted alcohol or drug abuse program; and

(ii) who are notified of the restrictions on redisclosure of the records in accordance with § 2.32 of these regulations.

(e) *Explanation of applicability*—(1) *Coverage.* These regulations cover information maintained about alcohol and drug abuse patients (including information on referral and intake) by any federally assisted alcohol or drug abuse program. Coverage includes, but is not limited to, those treatment or rehabilitation programs, employee assistance programs, programs within general hospitals, and private practitioners who hold themselves out as providing, and provide alcohol or drug abuse diagnosis, treatment, or referral for treatment.

(2) *How type of assistance affects scope of coverage.* (i) Any hospital which has Federal tax exempt status and operates an alcohol or drug abuse program must protect the confidentiality of information on any individual who applies for or receives referral, diagnosis, or treatment for alcohol or drug abuse in that program.

(ii) Any provider of care under Medicare or Medicaid must protect the confidentiality of information on any patient for whom Medicare or Medicaid reimbursement for alcohol and drug abuse services has been sought.

(iii) Any program which has a Federal license or registration to prescribe or administer a drug or controlled substance is required to protect the confidentiality of the records of any patient who is treated with that drug or substance.

(3) *How type of diagnosis affects coverage.* (a) These regulations cover any record of a diagnosis identifying a patient as an alcohol or drug abuser which is prepared in connection with the treatment or referral for treatment of alcohol or drug abuse. A diagnosis prepared for the purpose of treatment or referral for treatment but which is not so used is covered by these regulations. The following are not covered by these regulations:

(i) A diagnosis which is made solely for the purpose of providing evidence for use by law enforcement authorities;

(ii) A reference to a patient's alcoohol or drug abuse history in the course of treating a condition which is not related to alcohol or drug abuse; or

(iii) A diagnosis of drug overdose or alcohol intoxication which clearly shows that the individual involved is not an alchol or drug abuser (e.g., involuntary ingestion of alcohol or drugs or reaction to a prescribed dosage or one or more drugs).

§ 2.13 Coinfidentiality restrictions.

(a) *General.* The patient records to which these regulations apply may be disclosed or used only as permitted by these regulations and may not otherwise be disclosed or used in any civil, criminal, administrative, or legislative proceedings conducted by any Federal, State, or local authority. Any disclosure made under these regulations must be limited to that information which is necessary to carry out the purpose of the disclosure.

(b) *Unconditional compliance required.* The restrictions on disclosure and use in these regulations apply whether the holder of the information believes that the person seeking the information already has it, has other means of obtaining it, is a law enforcement or other official, has obtained a subpoena, or asserts any other justification for a disclosure or use which is not permitted by these regulations.

(c) *Acknowledging the persence of patients; Responding to requests.* (1) The presence of an identified patient in a facility or component of a facility which is publicly identified as a place where only alcohol or drug abuse diagnosis, treatment, or referral is provided may be acknowledged only if the patient's written consent is obtained in accordance with subpart C of these regulations or if an authorizing court order is entered in accordance with Subpart E of these regulations. The regulations permit acknowledgement of the presence of an identified patient in a facility or part of a facility if the facility is not publicy identified as only as alcohol or drug abuse diagnosis, treatment or referral facility, and if the acknowledgement does not reveal that the patient is an alcohol or drug abuser.

(2) Any answer to a request for a disclosure of patient records which is not permissible under these regulations must be made in a way that will not affirmatively reveal that an identified individual has been, or is being, diagnosed or treated for alcohol or drug abuse. An inquiring party may be given a copy of these regulations and advised that they restrict the disclosure of alcohol or drug abuse patient records, but may not be told affirmatively that the regulations restrict the disclosure of the records of an identified patient. The regulations do not restrict a disclosure that an identified individual is not and never has been a patient.

§ 2.14 Minor patients.

(a) *Definition of minor.* As used in these regulations the term "minor" means a person who has not attained the age of majority specified in the applicable State law, or if no age of majority is specified in the applicable State law, the age of eighteen years.

(b) *State law requiring parental consent to treatment*—(1) *Notifying parent or guardian of minor's application for treatment.* Notwithstanding any State law, any information regarding a minor's application for alcohol or drug abuse services may be communicated to the parent, guardian, or other person authorized under State law to act on behalf of the minor only if:

(i) The minor patient has given written consent to the disclosure in accordance with Subpart C of these regulations (if the minor patient does not give that consent and State law requires parental consent prior to any treatment, these regulations do not prohibit a refusal to provide treatment); or

(ii) In the judgment of the program director the minor applicant for services, because of a mental or physical condition, lacks the capacity to make a rational decision on whether to consent to the notification of his or her parent or guardian *and* the situation poses a substantial threat to the physical well being of any person which may be reduced by communicating relevant facts to the minor's parent or guardian.

(2) *Other disclosures with consent where State law requires parental consent to treatment.* In all other cases in which written patient consent is required under these regulations, that consent must be given by both the minor and his or her parent, guardian, or other person authorized under State law to act in the minor's behalf.

(c) *State law not requiring parental consent to treatment.* If a minor patient acting alone has the legal capacity under the applicable State law to apply for and obtain alcohol and drug abuse treatment, any written consent for a disclosure authorized under Subpart C of these regulations may be given only by the minor patient. This restriction includes, but is not limited to, a disclosure of patient identifying information to the parent or guardian of a minor patient for the purpose of obtaining financial reimbursement. These regulations do not prohibit a program from refusing to provide treatment until the minor patient consents to the disclosure necessary to obtain reimbursement, but refusal to provide treatment may be prohibited under a State or local law requiring the program to furnish the services irrespective of ability to pay.

§ 2.15 Incompetent and deceased patients.

(a) *Incompetent patients other than minors*—(1) *Adjudication of incompetence.* In the case of a patient who has been adjudicated as lacking the capacity, for any reason other than insufficient age, to manage his or her own affairs, any consent which is required under these regulations may be given by the guardian or other person authorized under State law to act in the patient's behalf.

(2) *No adjudication of incompetency.* For any period for which the program director determines that a patient, other than a minor or one who has been adjudicated incompetent, suffers from a medical condition that prevents knowing or effective action on his or her own behalf, the program director may exercise the right of the patient to consent to a disclosure under Subpart C of these regulations for the sole purpose of obtaining payment for services from a third party payer.

(b) *Deceased patients*—(1) *Vital statistics.* These regulations do not restrict the disclosure of patient identifying information relating to the cause of death of a patient under laws requiring the collection of death or other vital statistics or permitting inquiry into the cause of death.

(2) *Consent by personal representative.* Any other disclosure of information identifying a deceased patient as an alcohol or drug abuser is subject to these regulations. If a written consent to the disclosure is required, that consent may be given by an executor, administrator, or other personal representative appointed under applicable State law. If there is no such

appointment the consent may be given by the patient's spouse or, if none, by any responsible member of the patient's family.

§ 2.16 Security for written records.

(a) Written records which are subject to these regulations must be maintained:

(1) In a secure room, locked file cabinet, safe or other similar container when not in use; and

(2) In a manner that will permit the review of financial and administrative matters with no disclosure of clinical information and no disclosure of patient identifying information except where necessary for audit verification.

(b) Each program shall adopt in writing procedures which regulate and control access to and use of written records which are subject to these regulations.

§ 2.17 Undercover agents and informants.

(a) *Restrictions on placement.* Except as specifically authorized by a court order granted under § 2.66 of these regulations, no program may knowingly employ, or enroll as a patient, any undercover agent or informant.

(b) *Restriction on use of information.* No information obtained by an undercover agent or informant, whether or not that undercover agent or informant is placed in a program pursuant to an authorizing court order, may be used to criminally investigate or prosecute any patient.

§ 2.18 Restrictions on the use of identification cards.

No person may require any patient to carry on his or her person while away from the program premises any card or other object which would identify the patient as an alcohol or drug abuser. This section does not prohibit a person from requiring patients to use or carry cards or other identification objects on the premises of a program.

§ 2.19 Disposition of records by discontinued programs.

(a) *General.* If a program discontinues operations or is taken over or acquired by another program, it must purge patient identifying information from its records or destroy the records unless—

(1) The patient who is the subject of the records gives written consent (meeting the requirements of § 2.31) to a transfer of the records to the acquiring program or, if none, to any program designated in the consent (the manner of obtaining this consent must minimize the likelihood of a disclosure of patient identifying information to a third party); or

(2) There is a legal requirement that the records be kept for a period specified by law which does not expire until after the discontinuation or acquisition of the program.

(b) *Procedure where retention period required by law.* If paragraph (a)(2) of this section applies, the records must be:

(1) Sealed in envelopes or other containers labeled as follows: "Records of [insert name of program] required to be maintained under [insert citation to statute, regulation, or court order requiring that records be kept] until a date not later than [insert appropriate date];" and

(2) Held under the restrictions of these regulations by a responsible person who must, as soon as practicable after the end of the retention period specified on the label, destroy the records.

§ 2.20 Relationship to State laws.

The statutes authorizing these regulations (42 U.S.C. 290ee-3 and 42 U.S.C. 290dd-3) do not preempt the field of law which they cover to the exclusion of all State laws in that field. If a disclosure permitted under these regulations is prohibited under State law, neither these regulations nor the authorizing statutes may be construed to authorize any violation of that State law. However, no State law may either authorize or compel any disclosure prohibited by these regulations.

§ 2.21 Relationship to Federal statutes protecting research subjects against compulsory disclosure of their identity.

(a) *Research privilege discription.* There may be concurrent coverage of patient identifying information by these regulations and by administrative action taken under: Section 303(a) of the Public Health Service Act (42 U.S.C. 242a(a)) and the implementing regulations at 42 CFR Part 2a); or section 502(c) of the Controlled Substances Act (21 U.S.C. 872(c) and the implementing regulations at 21 CFR 1316.21). These "research privilege" statutes confer on the Secretary of Health and Human Services and on the Attorney General, respectively, the power to authorize researchers conducting certain types of research to withhold from all persons not connected with the research the names and other identifying information concerning individuals who are the subjects of the research.

(b) *Effect of concurrent coverage.* These regulations restrict the disclosure and use of information about patients, while administrative action taken under the research privilege statutes and implementing regulations protects a person engaged in applicable research from being compelled to disclose any identifying characteristics of the individuals who are the subjects of that research. The issuance under Subpart E of these regulations of a court order authorizing a disclosure of information about a patient does not affect an exercise of authority under these research privilege statutes. However, the research privilege granted under 21 CFR 291.505(g) to treatment programs using methadone for maintenance treatment does not protect from compulsory disclosure any information which is permitted to be disclosed under these regulations. Thus, if a court order entered in accordance with Subpart E of these regulations authorizes a methadone maintenance treatment program to disclose certain information about its patients, that program may not invoke the research privilege under 21 CFR 291.505(g) as a defense to a subpoena for that information.

§ 2.22 Notice to patients of Federal confidentiality requirements.

(a) *Notice required.* At the time of admission or as soon thereafter as the patient is capable of rational communication, each program shall:

(1) Communicate to the patient that Federal law and regulations protect the confidentiality of alcohol and drug abuse patient records; and

(2) Give to the patient a summary in writing of the Federal law and regulations.

(b) *Required elements of written summary.* The written summary of the Federal law and regulations must include:

(1) A citation to the Federal law and regulations.

(2) A description of the limited circumstances under which a program may disclose outside the program information identifying a patient as an alcohol or drug abuser.

(3) A description of the limited circumstances under which a program may acknowledge that an individual is present at a facility.

(4) A description of the circumstances under which alcohol or drug abuse patient records may be used to initiate or substantiate criminal charges against a patient.

(5) A statement that information related to a patient's commission of a crime on the premises of the program or against personnel of the program is not protected.

(6) A statement that the Federal law and regulations do not prohibit a program from giving a patient access to his or her own records.

(7) A statement of the criminal penalty for violation of the Federal law and regulations.

(8) An address where suspected violations of the Federal law and regulations may be reported.

(c) *Program options.* The program may devise its own notice or may use the sample notice in paragraph (d) to comply with the requirement to provide the patient with a summary in writing of the Federal law and regulations. In addition, the program may include in the written summary information concerning State law and any program policy not inconsistent with State and Federal law on the subject of confidentiality of alcohol and drug abuse patient records.

(d) *Sample notice.*

Confidentiality of Alcohol and Drug Abuse Patient Records

The confidentiality of alcohol and drug abuse patient records maintained by this program is protected by Federal law and regulations (42 U.S.C. 290dd-3, 42 U.S.C. 290ee-3 and 42 CFR Part 2). No information identifying a patient as an alcohol or drug abuser may be disclosed outside the program or those assisting the program in the provision of services:

(1) Unless the patient consents in writing;

(2) Unless the disclosure is allowed by a court order based upon a finding of good cause, or

(3) Unless the disclosure is to medical personnel for a medical emergency or to qualified personnel to conduct scientific research, management audits, financial audits, or program evaluation, but those qualified personnel may not redisclose any information which would identify any patient.

The program may not say that an individual is present at a facility if to do so would reveal that the patient is an alcohol or drug abuser unless the patient consents in writing to have his or her presence acknowledged or unless an authorizing court order is entered permitting that acknowledgment.

Unless allowed by a court order which meets the requirements of the regulations, no alcohol or drug abuse patient record may be used to initiate or substantiate any criminal charges against a patient, but the Federal law and regulations do not protect information related to a patient's commission of a crime on the premises of the program or against personnel of the program or a patient's threat to commit such a crime.

Under the regulations a program may (but is not required to) allow a patient to inspect and copy his or her record.

There is a criminal penalty for violation of Federal law or regulations requiring confidentiality of alcohol and drug abuse patient records: a fine of not more than $500 in the case of a first offense, and not more than $5,000 in the case of each subsequent offense.

Suspected violations may be reported either to the Director, National Institute on Drug Abuse or to the Director, National Institute on Alcohol Abuse and Alcoholism, both at 5600 Fishers Lane, Rockville, Maryland 20857. Suspected violations may also be reported to the United States Attorney for the judicial district in which the violation occurs.

§ 2.23. Patient access and restriction on use.

(a) *Patient access not prohibited.* These regulations do not prohibit a program from giving a patient access to his or her own records, including the opportunity to inspect and copy any records that the program maintains about the patient. The program is not required to obtain a patient's written consent or other authorization under these regulations in order to provide such access to the patient.

(b) *Restriction on use of information.* Information obtained by patient access to his or her patient record is subject to the restriction on use of this information to initiate or substantiate any criminal charges against the patient or to conduct any criminal investigation of the patient as provided for under §2.12(d)(1).

Subpart C—Disclosures With Patient's Consent

§ 2.31 Form of written consent.

(a) *Required elements.* A written consent to a disclosure under these regulations must include:

(1) The name of the program which is to make the disclosure.

(2) The name or title of the individual or the name of the organization to which disclosure is to be made.

(3) The name of the patient.

(4) The purpose of the disclosure.

(5) How much and what kind of information is to be disclosed.

(6) The signature of the patient and, when required for a patient who is a minor, the signature of a person authorized to give consent under § 2.14; or, when required for a patient who is incompetent or deceased, the signature of a person authorized to sign under § 2.15 in lieu of the patient.

(7) The date on which the consent is signed.

(8) A statement that the consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already acted in reliance on it. Acting in reliance includes the provision of treatment services in reliance on a valid consent to disclose information to a third party payer.

(9) The date, event, or condition upon which the consent will expire if not revoked before. This date, event, or condition must insure that the consent will last no longer than reasonably necessary to serve the purpose for which it is given.

(b) *Sample consent form.* The following form complies with paragraph (a) of this section, but other elements may be added.

1. I (name of patient) ☐ Request ☐ Authorize:
2. (name of program which is to make the disclosure) _____
3. To disclose: (kind and amount of information to be disclosed) _____

_____

4. To: (name or title of the person or organization to which disclosure is to be made) _____
5. For: (purpose of the disclosure) _____
6. Date (on which this consent is signed) _____
7. Signature of patient _____
8. Signature of parent or guardian (where required) _____
9. Signature of person authorized to sign in lieu of the patient (where required) _____
10. This consent is subject to revocation at any time except to the extent that the program which is to make the disclosure has already taken action in reliance on it. If not previously revoked, this consent will terminate upon: (specific date, event, or condition)

(c) *Expired, deficient, or false consent.* A disclosure may not be made on the basis of a consent which:

(1) Has expired;

(2) Does not comply with paragraph (a) of this section;

(3) Is known to have been revoked; or

(4) Is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

§ 2.32 Prohibition on redisclosure.

(a) *Notice to accompany disclosure.* Each disclosure made with the patient's written consent must be accompanied by the following written statement:

This information has been disclosed to you from records protected by Federal confidentiality rules (42 CFR Part 2). The Federal rules prohibit you from making any further disclosure of this information without the specific written consent of the person to whom it pertains or as otherwise permitted by 42 CFR Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose. The Federal rules restrict any use of the information to criminally investigate or prosecute any alcohol or drug abuse patient.

§ 2.33 Disclosures permitted with written consent.

If a patient consents to a disclosure of his or her records under § 2.31, a program may disclose those records in accordance with that consent to any individual or organization named in the consent, except that disclosures to central registries and in connection with criminal justice referrals must meet the requirements of § 2.34 and § 2.35, respectively.

§ 2.34 Disclosures to prevent multiple enrollments in detoxification and maintenance treatment programs.

(a) *Restrictions on disclosure.* A program may disclose patient records to a central registry or to any detoxification or maintenance treatment program not more than 200 miles away for the purpose of preventing the multiple enrollment of a patient only if:

(1) The disclosure is made when:

(i) The patient is accepted for treatment;

(ii) The type or dosage of the drug is changed; or

(iii) The treatment is interrupted, resumed or terminated.

(2) The disclosure is limited to:

(i) Patient identifying information;

(ii) Type and dosage of the drug; and

(iii) Relevant dates.

(3) The disclosure is made with the patient's written consent meeting the requirements of § 2.31, except that:

(i) The consent must list the name and address of each central registry and each known detoxification or maintenance treatment program to which a disclosure will be made; and

(ii) The consent may authorize a disclosure to any detoxification or maintenance treatment program established within 200 miles of the program after the consent is given without naming any such program.

(b) *Use of information limited to prevention of multiple enrollments.* A central registry and any detoxification or maintenance treatment program to which information is disclosed to prevent multiple enrollments may not redisclose or use patient identifying information for any purpose other than the prevention of multiple enrollments unless authorized by a court order under Subpart E of these regulations.

(c) *Permitted disclosure by a central registry to prevent a multiple enrollment.* When a member program asks a central registry if an identified patient is enrolled in another member program and the registry determines that the patient is so enrolled, the registry may disclose—

(1) The name, address, and telephone number of the member program(s) in which the patient is already enrolled to the inquiring member program; and

(2) The name, address, and telephone number of the inquiring member program to the member program(s) in which the patient is already enrolled. The member programs may communicate as necessary to verify that no error has been made and to prevent or eliminate any multiple enrollment.

(d) *Permitted disclosure by a detoxification or maintenance treatment program to prevent a multiple enrollment.* A detoxification or maintenance treatment program which has received a disclosure under this section and has determined that the patient is already enrolled may communicate as necessary with the program making the disclosure to verify that no error has been made and to prevent or eliminate any multiple enrollment.

§ 2.35 Disclosures to elements of the criminal justice system which have referred patients.

(a) A program may disclose information about a patient to those persons within the criminal justice system which have made participation in the program a condition of the disposition of any criminal proceedings against the patient or of the patient's parole or other release from custody if:

(1) The disclosure is made only to those individuals within the criminal justice system who have a need for the information in connection with their duty to monitor the patient's progress (e.g., a prosecuting attorney who is withholding charges against the patient, a court granting pretrial or posttrial release, probation or parole officers responsible for supervision of the patient); and

(2) The patient has signed a written consent meeting the requirements of § 2.31 (except paragraph (a)(8) which is inconsistent with the revocation provisions of paragraph (c) of this section) and the requirements of paragraphs (b) and (c) of this section.

(b) *Duration of consent.* The written consent must state the period during which it remains in effect. This period must be reasonable, taking into account:

(1) The anticipated length of the treatment;

(2) The type of criminal proceeding involved, the need for the information in connection with the final disposition of that proceeding, and when that final disposition will occur; and

(3) Such other factors as the program, the patient, and the person(s) who will receive the disclosure consider pertinent.

(c) *Revocation of consent.* The written consent must state whether it is revocable, and if so, the period during which it is revocable. The consent may be:

(1) Irrevocable until there has been a final disposition of the conditional release or other action in connection with which the consent was given; or

(2) Revocable upon the passage of a specified amount of time or the occurrence of a specified, ascertainable event.

(d) *Retrictions on redisclosure and use.* A person who receives patient information under this section may redisclose and us it only to carry out that person's official duties with regard to the patient's conditional release or other action in connection with which the consent was given.

Subpart D—Disclosures Without Patient Consent

§ 2.51 Medical emergencies.

(a) *General Rule.* Under the procedures required by paragraph (c) of this section, patient identifying information may be disclosed to medical personnel who have a need for information about a patient for the purpose of treating a condition which poses an immediate threat to the health of any individual and which requires immediate medical intevention.

(b) *Special Rule.* Patient identifying information may be disclosed to medical personnel of the Food and Drug Administration (FDA) who assert a reason to believe that the health of any individual may be threatened by an error in the manufacture, labeling, or sale of a product under FDA justisdiction, and that the information will be used for the exclusive purpose of notifying patients or their physicians of potential dangers.

(c) *Procedures.* (1) Prior to disclosure, the program shall make a reasonable effort to verify the medical personnel status of any proposed recipient of the disclosure.

(2) Immediately following disclosure, the program shall document the disclosure in the patient's records setting forth in writing:

(i) The name of the medical personnel to whom disclosure was made and their affiliation with any health care facility;

(ii) The name of the individual making the disclosure;

(iii) The date and time of the disclosure;

(iv) The nature of the emergency (or error, if the report was to FDA); and

(v) The details of the attempt to verify the medical personnel status of the recipient.

§ 2.52 Research activities.

(a) Patient identifying information may be disclosed for the purpose of conducting scientific research if the program director makes a determination that the recipient of the patient identifying information:

(1) Is qualified to conduct the research; and

(2) Has a research protocol under which the patient identifying information:

(i) Will be maintained in accordance with the security requirements of § 2.16 of these regulations (or more stringent requirements); and

(ii) Will not be redisclosed except as permitted under paragraph (b) of this section.

(b) A person conducting research may disclose patient identifying information obtained under paragraph (a) of this section only back to the program from which that information was obtained and may not identify any individual patient in any report of that research or otherwise disclose patient identities.

§ 2.53 Audit and evaluation activities.

(a) *Records not copied or removed.* If patient records are not copied or removed, patient identifying information may be disclosed in the course of a review of records on program premises to any person who agrees in writing to comply with the limitations on redisclosure and use in paragraph (c) of this section and who:

(1) Is paid to perform the audit or evaluation activity by a Federal, State, or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities; or

(2) Is determined by the program director to be qualified to conduct the audit or evaluation activities.

(b) *Copying or removal of records.* Records containing patient identifying information may be copied or removed from program premises by any person who:

(1) Agrees in writing to:

(i) Maintain the patient identifying information in accordance with the security requirements provided in § 2.16 of these regulations (or more stringent requirements);

(ii) Destroy all the patient identifying information upon completion of the audit or evaluation; and

(iii) Comply with the limitations on disclosure and use in paragraph (c) of this section; and

(2) Is paid to perform the audit or evaluation activity by a Federal, State or local governmental agency which provides financial assistance to the program or is authorized by law to regulate its activities.

(c) *Limitations on disclosure and use.* Patient identifying information disclosed under this section may be disclosed only back to the program from which it was obtained and used only to carry out an audit or evaluation purpose or to investigate or prosecute the program for criminal activities, as authorized by a court order entered under § 2.65 of these regulations.

Subpart E—Court Orders Authorizing Disclosure And Use

§ 2.61 Legal effect of order.

(a) *Effect.* An order of a court of competent jurisdiction entered under this subpart is a unique kind of court order. Its only purpose is to authorize a disclosure or use of patient information which would otherwise be prohibited by 42 U.S.C. 290ee–3, 42 U.S.C. 290dd–3 and these regulations. Such an order does not compel disclosure. A subpoena or a similar legal mandate must be issued in order to compel disclosure. This mandate may be entered at the same time as, and accompany, an authorizing court order entered under these regulations.

(b) *Examples.* (1) A person holding records subject to these regulations receives a subpoena for those records; a response to the subpoena is not permitted under the regulations unless an authorizing court order is entered. The person may not disclose the records in response to the subpoena unless a court of competent jurisdiction enters an authorizing order under these regulations.

(2) An authorizing court order is entered under these regulations, but the person authorized does not want to make the disclosure. If there is no subpoena or other compulsory process, or a subpoena for the records has expired or been quashed, that person may refuse to make the disclosure. Upon the entry of a valid subpoena or other compulsory process the person authorized to disclose must disclose, unless there is a valid legal defense to the process other than the confidentiality restrictions of these regulations.

§ 2.62 Order not applicable to records disclosed without consent to researchers, auditors and evaluators.

A court under these regulations may not authorize qualified personnel, who have received patient identifying information without consent for the purpose of conducting research, audit or evaluation, to disclose that information or use it to conduct any criminal investigation or prosecution of a patient. However, a court order under § 2.65 may authorize disclosue and use of records to investigate or prosecute qualified personnel holding the records.

§ 2.63 Procedures and criteria for orders authorizing disclosures for noncriminal purposes.

(a) *Application.* An order authorizing the disclosure of patient records for purposes other than criminal investigation or prosecution may be applied for by any person having a legally recognized interest in the disclosure which is sought. The application may be filed separately or as part of a pending civil action in which it appears that the patient records are needed to provide evidence. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the patient is the applicant or has given a written consent (meeting the requirements of these regulations) to disclosure or the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice.* The patient and the person holding the records from whom disclosure is sought must be given:

(1) Adequate notice in a manner which will not disclose patient identifying information to other persons; and

(2) An opportunity to file a written response to the application, or to appear in person.

(c) *Review of evidence; Conduct of hearing.* Any oral argument, review of evidence, or hearing on the application must be held in the judge's chambers or in some manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceeding, the patient, or the person holding the record. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria for entry of order.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find that:

(1) Other ways of obtaining the information are not available or would not be effective; and

(2) The public interest and need for the disclosure outweigh the potential injury to the patient, the physician-patient relationship and the treatment services.

(e) *Content of order.* An order authorizing a disclosure must:

(1) Limit disclosure to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those persons whose need for information is the basis for the order; and

(3) Include such other measures as are necessary to limit disclosure for the protection of the patient, the physician-patient relationship and the treatment services.

§ 2.64 Procedures and criteria for orders authorizing disclosure and use of records to criminally investigate or prosecute patients.

(a) *Application.* An order authorizing the disclosure or use of patient records to criminally investigate or prosecute a patient may be applied for by the person holding the records or by any person conducting investigative or prosecutorial activities with respect to the enforcement of criminal laws. The application may be filed separately, as part of an application for a subpoena or other compulsory process, or in a pending criminal action. An application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny.

(b) *Notice and hearing.* Unless an order under § 2.65 is sought with an order under this section, the person holding the records must be given:

(1) Adequate notice (in a manner which will not disclose patient identifying information to third parties) of an application by a person performing a law enforcement function;

(2) An opportunity to appear and be heard; and

(3) An opportunity to be represented by counsel independent of counsel for an applicant who is a person performing a law enforcement function.

(c) *Review of evidence; Conduct of hearings.* Any oral argument, review of evidence, or hearing on the application shall be held in the judge's chambers or in some other manner which ensures that patient identifying information is not disclosed to anyone other than a party to the proceedings, the patient, or the person holding the records. The proceeding may include an examination by the judge of the patient records referred to in the application.

(d) *Criteria.* A court may authorize the disclosure and use of patient records for the purpose of conducting a criminal investigation or prosecution of a patient only if the court finds that all of the following criteria are met:

(1) The crime involved causes or directly threatens loss of life or serious bodily injury, such as homicide, rape, kidnapping, armed robbery, assault with a deadly weapon, child abuse and neglect, or the sale of illicit drugs.

(2) There is a reasonable likelihood that the records will disclose information of substantial value in the investigation or prosecution.

(3) There is no other practicable way of obtaining the information.

(4) The potential injury to the patient, to the physician-patient relationship and to the ability of the person holding the records to provide services to other patients is outweighed by the public interest and the need for the disclosure.

(5) If the applicant is a person performing a law enforcement function that:

(i) The person holding the records has been afforded the opportunity to be represented by independent counsel; and

(ii) Any person holding the records which is an entity within Federal, State, or local government has in fact been represented by counsel independent of the applicant.

(e) *Content of order.* Any order authorizing a disclosure or use of patient records under this section must:

(1) Limit disclosure and use to those parts of the patient's record which are essential to fulfill the objective of the order;

(2) Limit disclosure to those law enforcement and prosecutorial officials who are responsible for, or are conducting, the investigation or prosecution, and limit their use of the records to investigation and prosecution of the crime or suspected crime causing or directly threatening loss of life or serious bodily injury which is specified in the application; and

(3) Include such other measures as are necessary to limit disclosure and use to the fulfillment of only that public interest and need found by the court.

§ 2.65 Procedures and criteria for orders authorizing disclosure and use of records to investigate or prosecute a program or the person holding the records.

(a) *Application.* (1) An order authorizing the disclosure or use of patient records to criminally or administratively investigate or prosecute a program or the person holding the records (or employees or agents of that program or person) may be applied for by any administrative, regulatory, supervisory, investigative, law enforcement, or prosecutorial agency having jurisdiction over the program's or person's activities.

(2) The application may be filed separately or as part of a pending civil or criminal action against a program or the person holding the records (or agents or employees of the program or person) in which it appears that the patient records are needed to provide material evidence. The application must use a fictitious name, such as John Doe, to refer to any patient and may not contain or otherwise disclose any patient identifying information unless the court has ordered the record of the proceeding sealed from public scrutiny or the patient has given a written consent (meeting the requirements of § 2.31 of these regulations) to that disclosure.

(b) *Notice.* An application under this section may, in the discretion of the court, be granted without notice. However, upon implementation of any order so granted, the program or person holding the records and the patients whose records are to be disclosed must be afforded an opportunity to seek revocation or amendment of that order.

(c) *Requirements for order.* An order under this section must be entered in accordance with, and comply with the requirements of, paragraphs (d) and (e) of § 2.63 of these regulations.

(d) *Limitations on disclosure and use of patient identifying information.* (1) An order entered under this section must require the deletion of patient identifying information from any documents made available to the public.

(2) No information obtained under this section may be used to conduct any investigation or prosecution of a patient, or be used as the basis for an application for an order under § 2.64 of these regulations.

§ 2.66 Orders authorizing the use of undercover agents and informants to criminally investigate employees or agents of a program.

(a) *Application.* A court order authorizing the placement of an undercover agent or informant in a program as an employee or patient may be applied for by any law enforcement or prosecutorial agency which has reason to believe that employees or agents of the program are engaged in criminal misconduct.

(b) *Notice.* The program director must be given adequate notice of the application and an opportunity to appear and be heard, unless the application asserts a belief that:

(1) The program director is involved in the criminal activities to be investigated by the undercover agent or informant; or

(2) The program director will intentionally or unintentionally disclose the proposed placement of an undercover agent or informant to the employees or agents who are suspected of criminal activities.

(c) *Criteria.* An order under this section may be entered only if the court determines that good cause exists. To make this determination the court must find:

(1) There is reason to believe that an employee or agent of the program is engaged in criminal activity;

(2) Other ways of obtaining evidence of this criminal activity are not available or would not be effective; and

(3) The public interest and need for the placement of an undercover agent or informant in the program outweigh the potential injury to patients of the program, physician-patient relationships and the treatment services.

(d) *Content of order.* An order authorizing the placement of an undercover agent or informant in a program must:

(1) Specifically authorize the placement of an undercover agent or an informant;

(2) Limit the total period of the placement to six months;

(3) Prohibit the undercover agent or informant from disclosing any patient identifying information obtained from the placement except as necessary to criminally investigate or prosecute employees or agents of the program; and

(4) Include any other measures which are appropriate to limit any potential disruption of the program by the placement and any potential for a real or apparent breach of patient confidentiality.

(e) *Limitation on use of information.* No information obtained by an undercover agent or informant placed under this section may be used to criminally investigate or prosecute any patient or as the basis for an application for an order under § 2.64 of these regulations.

[FR Doc. 83-22580 Filed 8-24-83; 8:45 am]
BILLING CODE 4160-20-M